
Federal Register

**Monday,**
**December 10, 2007**

## Part VII

# Department of Health and Human Services

**Semiannual Regulatory Agenda**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Office of the Secretary**

**21 CFR Ch. I**

**42 CFR Chs. I-V**

**45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII**

**Regulatory Agenda**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Semiannual Regulatory Agenda.

**SUMMARY:** The Regulatory Flexibility Act of 1980 and Executive Order 12866 require issuance of the following inventory of the rulemaking actions being developed by the Department. The purpose is to encourage public participation in the regulatory process by providing, at as early a stage as possible, summarized information about regulatory actions under consideration.

**FOR FURTHER INFORMATION CONTACT:** Ann C. Agnew, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

**SUPPLEMENTARY INFORMATION:** The capsulized information provided presents for public scrutiny a forecast of the rulemaking activities that the Department expects to undertake over the foreseeable future. We focus primarily on those areas of work expected to result in publication of Notices of Proposed Rulemaking or Final Rules within the next 12 months.

For this edition of the Department of Health and Human Services' regulatory agenda, the most important significant regulatory actions and a Statement of Regulatory Priorities are included in The Regulatory Plan, which appears in both the online Unified Agenda and in part II of the **Federal Register** that includes the Unified Agenda**.**

In addition, beginning with the fall 2007 edition, the Internet will be the basic means for disseminating the Unified Agenda. The complete Unified Agenda will be available online at www.reginfo.gov, in a format that offers users a greatly enhanced ability to obtain information from the Agenda database.

Because publication in the **Federal Register** is mandated for the regulatory flexibility agendas required by the Regulatory Flexibility Act (5 U.S.C. 602), the Department of Health and Human Services' printed agenda entries include only:

(1) rules that are in the Agency's regulatory flexibility agenda, in accordance with the Regulatory Flexibility Act, because they are likely to have a significant economic impact on a substantial number of small entities; and

(2) any rules that the Agency has identified for periodic review under section 610 of the Regulatory Flexibility Act.

Printing of these entries is limited to fields that contain information required by the Regulatory Flexibility Act's Agenda requirements. Additional information on these entries is available in the Unified Agenda published on the Internet. In addition, for fall editions of the Agenda, the entireRegulatory Plan will continue to be printed in the **Federal Register**, as in past years, including the Health and Human Services' Regulatory Plan.

We welcome the views of all concerned with regard to these planned rulemakings. Comments may be directed to the agency officials cited in each of the summaries below; if early attention at the Secretary's level appears needed, comments should be sent to: Ann C. Agnew, Executive Secretary to the Department, Room 603H, 200 Independence Avenue SW., Washington, DC 20201.

**Dated:** September 26, 2007.

**Ann C. Agnew,**

*Executive Secretary to the Department.*

### Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|---|---|---|
| 311 | Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth | 0930–AA10 |

### Centers for Disease Control and Prevention—Final Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|---|---|---|
| 312 | Control of Communicable Diseases, Interstate and Foreign Quarantine **(Reg Plan Seq No. 37)** | 0920–AA12 |

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

### Food and Drug Administration—Prerule Stage

| Sequence Number | Title | Regulation Identifier Number |
|---|---|---|
| 313 | Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients **(Section 610 Review)** | 0910–AF75 |
| 314 | Medical Devices: Classification/Reclassification; Restricted Devices; Analyte Specific Reagents **(Section 610 Review)** | 0910–AF76 |

**HHS**

## Food and Drug Administration—Prerule Stage (Continued)

| Sequence Number | Title | Regulation Identifier Number |
|---|---|---|
| 315 | Amended Economic Impact Analysis of Final Rule on User Labeling on Natural Rubber-Containing Medical Device **(Section 610 Review)** | 0910–AF77 |
| 316 | Financial Disclosure by Clinical Investigators **(Section 610 Review)** | 0910–AF79 |
| 317 | Beverages: Bottled Water **(Section 610 Review)** | 0910–AF80 |
| 318 | Food Labeling; Nutrient Content Claims: Definition for ''High Potency'' and Definition of ''Antioxidant'' for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods **(Section 610 Review)** | 0910–AF83 |

## Food and Drug Administration—Proposed Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|---|---|---|
| 319 | Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics **(Reg Plan Seq No. 38)** | 0910–AC52 |
| 320 | Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling **(Reg Plan Seq No. 39)** | 0910–AF11 |
| 321 | Over-the-Counter (OTC) Drug Review—External Analgesic Products | 0910–AF35 |
| 322 | Over-the-Counter (OTC) Drug Review—Internal Analgesic Products | 0910–AF36 |
| 323 | Over-the-Counter (OTC) Drug Review—Oral Health Care Products | 0910–AF40 |
| 324 | Over-the-Counter (OTC) Drug Review—Sunscreen Products | 0910–AF43 |
| 325 | Label Requirement for Food That Has Been Refused Admission Into the United States **(Reg Plan Seq No. 40)** | 0910–AF61 |
| 326 | Over-the-Counter (OTC) Drug Review—Poison Treatment Drug Products | 0910–AF68 |
| 327 | Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products | 0910–AF69 |
| 328 | Over-the-Counter (OTC) Drug Review—Urinary Analgesic Drug Products | 0910–AF70 |

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

## Food and Drug Administration—Final Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|---|---|---|
| 329 | Safety Reporting Requirements for Human Drug and Biological Products | 0910–AA97 |
| 330 | Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements **(Reg Plan Seq No. 43)** | 0910–AB88 |
| 331 | Prevention of Salmonella Enteritidis in Shell Eggs **(Reg Plan Seq No. 44)** | 0910–AC14 |
| 332 | Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs | 0910–AC35 |
| 333 | Positron Emission Tomography Drugs; Current Good Manufacturing Practices | 0910–AC55 |
| 334 | Cochineal Extract and Carmine Label Declaration | 0910–AF12 |
| 335 | Charging for Investigational Drugs | 0910–AF13 |
| 336 | Expanded Access to Investigational Drugs for Treatment Use **(Reg Plan Seq No. 46)** | 0910–AF14 |
| 337 | Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products | 0910–AF31 |
| 338 | Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products | 0910–AF32 |
| 339 | Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products | 0910–AF33 |
| 340 | Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products | 0910–AF34 |
| 341 | Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use | 0910–AF37 |
| 342 | Over-the-Counter (OTC) Drug Review—Laxative Drug Products | 0910–AF38 |
| 343 | Over-the-Counter (OTC) Drug Review—Skin Protectant Products | 0910–AF42 |
| 344 | Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products | 0910–AF44 |
| 345 | Over-the-Counter (OTC) Drug Review—Weight Control Products | 0910–AF45 |
| 346 | Substances Prohibited From Use in Animal Food or Feed To Prevent the Transmission of Bovine Spongiform Encephalopathy | 0910–AF46 |
| 347 | Over-the-Counter (OTC) Drug Review—Antacid Products | 0910–AF52 |
| 348 | Over-the-Counter (OTC) Drug Review—Skin Bleaching Products | 0910–AF53 |

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

**HHS**

## Food and Drug Administration—Long-Term Actions

| Sequence Number | Title | Regulation Identifier Number |
|---|---|---|
| 349 | Requirements for Submission of In Vivo Bioequivalence Data | 0910–AC23 |
| 350 | Health Claims | 0910–AF09 |
| 351 | Over-the-Counter (OTC) Drug Review—Ophthalmic Products | 0910–AF39 |
| 352 | Over-the-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products | 0910–AF51 |
| 353 | Over-the-Counter (OTC) Drug Review—Stimulant Drug Products | 0910–AF56 |
| 354 | Over-the-Counter Antidiarrheal Drug Products | 0910–AF63 |
| 355 | Food Labeling; Serving Sizes; Reference Amount for Baking Powder, Baking Soda, and Pectin **(Section 610 Review)** | 0910–AF99 |

## Food and Drug Administration—Completed Actions

| Sequence Number | Title | Regulation Identifier Number |
|---|---|---|
| 356 | Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality Systems Regulations **(Completion of a Section 610 Review)** | 0910–AF71 |
| 357 | Package Size Limitation for Sodium Phosphates Oral Solution and Warning and Direction Statements for Oral and Rectal Sodium Phosphates for Over-the-Counter Laxative Use **(Section 610 Review)** | 0910–AF73 |
| 358 | Over-the-Counter Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use: Required Alcohol Warning **(Section 610 Review)** | 0910–AF74 |

## Centers for Medicare & Medicaid Services—Proposed Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|---|---|---|
| 359 | Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P) **(Section 610 Review)** | 0938–AG81 |
| 360 | Revisions to HIPAA Code Sets (CMS-0013-P) | 0938–AN25 |
| 361 | Home and Community-Based Services (HCBS) State Plan Option (CMS-2249-P) | 0938–AO53 |
| 362 | Prospective Payment System for Long-Term Care Hospitals RY 2009: Annual Payment Rate Updates (CMS-1393-P) | 0938–AO94 |
| 363 | Establishing Additional Medicare Provider and Supplier Enrollment Safeguards (CMS-6045-P) | 0938–AP01 |
| 364 | Hospice Wage Index for FY 2009 (CMS-1548-P) | 0938–AP14 |
| 365 | Changes to the Hospital Inpatient Prospective Payment Systems and FY 2009 Rates (CMS-1390-P) | 0938–AP15 |
| 366 | Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2009 (CMS-1404-P) **(Reg Plan Seq No. 50)** | 0938–AP17 |

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

## Centers for Medicare & Medicaid Services—Final Rule Stage

| Sequence Number | Title | Regulation Identifier Number |
|---|---|---|
| 367 | End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-F) **(Section 610 Review) (Reg Plan Seq No. 52)** | 0938–AG82 |
| 368 | Hospice Care Conditions of Participation (CMS-3844-F) **(Section 610 Review) (Reg Plan Seq No. 53)** | 0938–AH27 |

References in boldface appear in the Regulatory Plan in part II of this issue of the **Federal Register**.

## Centers for Medicare & Medicaid Services—Long-Term Actions

| Sequence Number | Title | Regulation Identifier Number |
|---|---|---|
| 369 | Hospital Conditions of Participation: Laboratory Services (CMS-3014-F) **(Section 610 Review)** | 0938–AJ29 |

## HHS

Centers for Medicare & Medicaid Services—Long-Term Actions (Continued)

| Sequence Number | Title | Regulation Identifier Number |
|---|---|---|
| 370 | Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-6006-F) | 0938–AO84 |
| 371 | Medicaid Graduate Medical Education (CMS-2279-F) **(Section 610 Review)** | 0938–AO95 |

Centers for Medicare & Medicaid Services—Completed Actions

| Sequence Number | Title | Regulation Identifier Number |
|---|---|---|
| 372 | Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (CMS-1810-F) | 0938–AK67 |
| 373 | Competitive Acquisition for Certain Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies (CMS-1270-F) | 0938–AN14 |
| 374 | Medicare Part B Competitive Acquisition of Outpatient Drugs and Biologicals (CMS-1325-F) | 0938–AN58 |
| 375 | Medicaid Prescription Drugs—Average Manufacturer Price (CMS-2238-FC) | 0938–AO20 |
| 376 | Prospective Payment System for Long-Term Care Hospitals RY 2008: Annual Payment Rate Updates and Policy Changes (CMS-1529-F) | 0938–AO30 |
| 377 | Home Health Prospective Payment System Refinements and Rate Update for Calendar Year 2008 (CMS-1541-F) | 0938–AO32 |
| 378 | Cost Limits for Governmentally Operated Providers (CMS-2258-FC) **(Completion of a Section 610 Review)** | 0938–AO57 |
| 379 | Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2008 (CMS-1551-F) | 0938–AO63 |
| 380 | Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2008 (CMS-1545-F) | 0938–AO64 |
| 381 | Changes to the Hospital Inpatient Prospective Payment Systems and FY 2008 Rates (CMS-1533-FC) | 0938–AO70 |
| 382 | Hospice Wage Index for FY 2008 (CMS-1539-F) | 0938–AO72 |
| 383 | Revised Payment System for Services Furnished in Ambulatory Surgical Centers (ASCs) Effective January 1, 2008 (CMS-1517-F) | 0938–AO73 |
| 384 | Fee Schedule for Payment of Ambulance Services—Update for CY 2008 (CMS-1552-N) | 0938–AO85 |

## Department of Health and Human Services (HHS) — Proposed Rule Stage

## Substance Abuse and Mental Health Services Administration (SAMHSA)

### 311. REQUIREMENTS GOVERNING THE USE OF SECLUSION AND RESTRAINT IN CERTAIN NONMEDICAL COMMUNITY–BASED FACILITIES FOR CHILDREN AND YOUTH

**Legal Authority:** PL 106–310, 42 USC 290jj to 290jj–2

**Abstract:** The Secretary is required by statute to publish regulations governing States that license nonmedical, community-based residential facilities for children and youth. The regulation requires States to develop licensing rules and monitoring requirements concerning behavior management practice that will ensure compliance; requires States to develop and implement such licensing rules and implementation requirements within one year; and ensures that States require such facilities to have adequate staff, and that the States provide training for professional staff.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 02/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

**Agency Contact:** Paolo Del Vecchio, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Room 13–103, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–2619

**RIN:** 0930–AA10

## Department of Health and Human Services (HHS) — Final Rule Stage

## Centers for Disease Control and Prevention (CDC)

### 312. CONTROL OF COMMUNICABLE DISEASES, INTERSTATE AND FOREIGN QUARANTINE

**Regulatory Plan:** This entry is Seq. No. 37 in part II of this issue of the **Federal Register**.

**RIN:** 0920–AA12

## Department of Health and Human Services (HHS) — Prerule Stage

## Food and Drug Administration (FDA)

### 313. STATUS OF CERTAIN ADDITIONAL OVER–THE–COUNTER DRUG CATEGORY II AND III ACTIVE INGREDIENTS (SECTION 610 REVIEW)

**Legal Authority:** 5 USC 610

**Abstract:** Section 310.545 (21 CFR part 310.545) codifies a final rule that was issued stating certain first aid antiseptic, vaginal contraceptive, and antimicrobial diaper rash ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective and are misbranded. This rule took into consideration the reports and recommendations of various OTC drug advisory review panels and public comment on proposed Agency regulations. Based on the absence of substantive comments in opposition to the Agency's proposed nonmonograph status for various ingredients, as well as the failure of interested parties to submit new data or information to FDA, the Agency determined that the presence of the subject ingredients in an OTC drug product would result in that product not being generally recognized as safe and effective and would result in misbranding.

FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in section 310.545. The purpose of this review is to determine whether the regulation in section 310.545 should be continued without change, or whether it should be further amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for the regulation in section 310.545; (2) the nature of the complaints or comments received concerning the regulation in section 310.545; (3) the complexity of the regulations in section 310.545; (4) the extent to which the regulation in section 310.545 overlaps, duplicates, or conflicts with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed for the products still subject to the regulation in section 310.545.

The section 610 review will be carried out along with a regulatory review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the Agency's regulatory program more effective in achieving its goals, less burdensome, or in greater alignment with the President's priorities and the principles set forth in the Executive order.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| Begin Review of Current Regulation | 12/01/06 | |
| End Review | 12/00/07 | |

**Regulatory Flexibility Analysis Required:** No

**Agency Contact:** Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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**RIN:** 0910–AF75

### 314. MEDICAL DEVICES: CLASSIFICATION/ RECLASSIFICATION; RESTRICTED DEVICES; ANALYTE SPECIFIC REAGENTS (SECTION 610 REVIEW)

**Legal Authority:** 21 USC 351; 21 USC 352; 21 USC 360j

**Abstract:** FDA is initiating a review under section 610 of the Regulatory Flexibility Act for two regulations in part 809. The purpose of this review is to determine if 21 CFR part 809.10 and 809.30 should be continued without change, or should be amended or rescinded to minimize adverse economic impact on small entities. FDA is soliciting and will consider comments on the following: 1) The continued need for 21 CFR part 809.10 and 809.30; 2) the nature of complaints or comments received concerning 21 CFR part 809.10 and 809.30; 3) the complexity of 21 CFR part 809.10 and 809.30; 4) the extent to which 21 CFR part 809.10 and 809.30 overlap, duplicate, or conflict with other Federal, State, or local government rules; and 5) the degree to which technology, economic conditions, or other factors have changed in the area affected by 21 CFR part 809.10 and 809.30.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| Begin Review of Current Regulation | 04/01/07 | |
| End Review | 11/00/07 | |

**Regulatory Flexibility Analysis Required:** No

**Agency Contact:** Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ–215), PI50 RM150F, 1350 Piccard Drive, Rockville, MD 20850
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**RIN:** 0910–AF76

### 315. AMENDED ECONOMIC IMPACT ANALYSIS OF FINAL RULE ON USER LABELING ON NATURAL RUBBER–CONTAINING MEDICAL DEVICE (SECTION 610 REVIEW)

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 357; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 374

**Abstract:** FDA is initiating a review of the regulations in part 801 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine, consistent with stated objectives and applicable statutes, whether the regulations in part 801 should be continued without change, amended, or rescinded in order to minimize any significant economic impact on a substantial number of small entities. FDA will consider and is soliciting comments on the following: 1) The continued need for the regulation; 2) the nature of complaints or comments received concerning the regulation; 3) the complexity of the regulation; 4) the extent to which a regulation in part 801 overlaps, duplicates, or conflicts with other Federal rules, and to the extent feasible, with State and local government rules; and 5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| Final Action | 09/30/97 | 62 FR 51021 |
| Final Action Effective | 09/30/98 | |
| Begin Review of Current Regulation | 01/02/07 | |
| End Review of Current Regulation | 12/00/07 | |

**Regulatory Flexibility Analysis Required:** No

**Agency Contact:** Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ–215), PI50 RM150F, 1350 Piccard Drive, Rockville, MD 20850
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**RIN:** 0910–AF77

### 316. FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS (SECTION 610 REVIEW)

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360j; 21 USC 371; 21 USC 372; 21 USC 373; 21 USC 374; 21 USC 375; 21 USC 376; 21 USC 379; 42 USC 262

**Abstract:** FDA is undertaking a review of 21 CFR part 54, under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in part 54 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statues, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for the regulations in part 54; (2) the nature of complaints or comments received concerning the regulations in part 54; (3) the complexity of the regulations in part 54, (4) the extent to which the regulations in part 54 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in part 54.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| Begin Review of Current Regulation | 12/01/06 | |
| End Review | 12/00/07 | |

**Regulatory Flexibility Analysis Required:** No

**Agency Contact:** Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Suite 1101 (HFD–7), 5515 Security Lane, Rockville, MD 20852
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**RIN:** 0910–AF79

### 317. BEVERAGES: BOTTLED WATER (SECTION 610 REVIEW)

**Legal Authority:** 21 USC 321; 21 USC 341; 21 USC 343; 21 USC 343–1; 21 USC 348; 21 USC 349; 21 USC 371; 21 USC 379e

**Abstract:** Section 165.110 (21 CFR part 165.110) describes requirements for identity and quality standards for bottled water. FDA is undertaking a review of section 165.110 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in section 165.110 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the regulations in section 165.110; (2) the nature of complaints or comments received concerning the regulations in section 165.110; (3) the complexity of the regulations; (4) the extent to which the regulations in section 165.110 overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in section 165.110.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| Begin Review | 03/01/07 | |
| End Review | 12/00/07 | |

**Regulatory Flexibility Analysis Required:** Undetermined

**Agency Contact:** David Zorn, Lead Economist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, ORP (HFS–020),

**HHS—FDA** **Prerule Stage**

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**RIN:** 0910–AF80

### 318. FOOD LABELING; NUTRIENT CONTENT CLAIMS: DEFINITION FOR ''HIGH POTENCY'' AND DEFINITION OF ''ANTIOXIDANT'' FOR USE IN NUTRIENT CONTENT CLAIMS FOR DIETARY SUPPLEMENTS AND CONVENTIONAL FOODS (SECTION 610 REVIEW)

**Legal Authority:** 15 USC 1453; 15 USC 1454; 15 USC 1455; 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

**Abstract:** Section 101.54 (21 CFR part 101.54) describes the requirements for when the terms ''high potency'' and ''antioxidant'' may be used on the label or in the labeling of foods, including dietary supplements. Section 101.60 (21 CFR part 101.60) describes the requirements for when the terms ''low calorie'' or ''reduced calorie'' may be used on the label or in the labeling of such foods. FDA is undertaking a review of sections 101.54 and 101.60 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the regulations in sections 101.54 and 101.60; (2) the nature of complaints or comments received concerning the regulations; (3) the complexity of the regulations; (4) the extent to which the regulations in sections 101.54 and 101.60 overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in sections 101.54 and 101.60.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| Begin Review | 12/01/06 | |
| End Review | 11/00/07 | |

**Regulatory Flexibility Analysis Required:** Undetermined

**Agency Contact:** David Zorn, Lead Economist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, ORP (HFS–020), 5100 Paint Branch Parkway, College Park, MD 20740
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**RIN:** 0910–AF83

## Department of Health and Human Services (HHS)
## Food and Drug Administration (FDA)

**Proposed Rule Stage**

### 319. ELECTRONIC SUBMISSION OF DATA FROM STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS

**Regulatory Plan:** This entry is Seq. No. 38 in part II of this issue of the **Federal Register**.

**RIN:** 0910–AC52

### 320. CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS; REQUIREMENTS FOR PREGNANCY AND LACTATION LABELING

**Regulatory Plan:** This entry is Seq. No. 39 in part II of this issue of the **Federal Register**.

**RIN:** 0910–AF11

### 321. OVER–THE–COUNTER (OTC) DRUG REVIEW—EXTERNAL ANALGESIC PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. These actions will address external analgesic drug products.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 12/00/08 | |
| Final Action | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF35

### 322. OVER–THE–COUNTER (OTC) DRUG REVIEW—INTERNAL ANALGESIC PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses products labeled to relieve upset stomach associated with overindulgence in food and drink and to relieve symptoms associated with a hangover. The second action addresses products marketed for children under 2 years old and weight- and age-based dosing for children's products. The third action addresses combination products containing the analgesic acetaminophen or aspirin and sodium bicarbonate used as an antacid ingredient. The fourth action addresses other miscellaneous issues relating to

internal analgesics. The fifth document finalizes the document regarding the required warnings and other labeling. The last document finalizes the Internal Analgesic Products monograph.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM (Amendment) (Required Warnings and Other Labeling) | 12/26/06 | 71 FR 77314 |
| NPRM Comment Period End | 05/25/07 | |
| NPRM (Amendment) (Overindulgence/ Hangover) | 06/00/08 | |
| NPRM (Amendment) (Pediatric) | 12/00/08 | |
| NPRM (Amendment) (Combinations with Sodium Bicarbonate) | 06/00/08 | |
| NPRM (Amendment) (Miscellaneous Issues) | 12/00/08 | |
| Final Action (Required Warnings and Other Labeling) | 06/00/08 | |
| Final Action (Internal Analgesics) | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF36

### 323. OVER–THE–COUNTER (OTC) DRUG REVIEW—ORAL HEALTH CARE PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will address oral health care products used to reduce or prevent dental plaque and gingivitis.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| ANPRM (Plaque Gingivitis) | 05/29/03 | 68 FR 32232 |
| NPRM (Plaque Gingivitis) | 12/00/08 | |
| Final Action | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF40

### 324. OVER–THE–COUNTER (OTC) DRUG REVIEW—SUNSCREEN PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action addresses sunscreen formulation, labeling, and testing requirements for both ultraviolet B (UVB) and ultraviolet A (UVA) radiation protection, and the other action addresses combination products containing sunscreen and insect repellent ingredients.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| ANPRM (Sunscreen and Insect Repellent) | 02/22/07 | 72 FR 7941 |
| ANPRM Comment Period End | 05/23/07 | |
| NPRM (UVA/UVB) | 08/27/07 | 72 FR 49070 |
| NPRM (Sunscreen and Insect Repellent) | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF43

### 325. LABEL REQUIREMENT FOR FOOD THAT HAS BEEN REFUSED ADMISSION INTO THE UNITED STATES

**Regulatory Plan:** This entry is Seq. No. 40 in part II of this issue of the **Federal Register**.

**RIN:** 0910–AF61

### 326. OVER–THE–COUNTER (OTC) DRUG REVIEW—POISON TREATMENT DRUG PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the ingredient ipecac syrup.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM (IPECAC) | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF68

### 327. OVER–THE–COUNTER (OTC) DRUG REVIEW—TOPICAL ANTIMICROBIAL DRUG PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355;

21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses food handler products. The second action addresses testing requirements. The last action addresses healthcare antiseptic products.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM (Food Handlers) | 12/00/08 | |
| NPRM (Testing) | 06/00/08 | |
| Final Action (Healthcare) | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF69

### 328. OVER–THE–COUNTER (OTC) DRUG REVIEW—URINARY ANALGESIC DRUG PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the products used for urinary pain relief.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM (Urinary Analgesic) | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF70

## Department of Health and Human Services (HHS)
## Food and Drug Administration (FDA)

**Final Rule Stage**

### 329. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

**Legal Authority:** 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262; 42 USC 263; 42 USC 263a to 263–n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360b to 360j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381

**Abstract:** These regulations are one component of the Secretary's initiative to reduce medical errors. The final rule would amend the expedited and periodic safety reporting regulations for human drugs and biological products to revise certain definitions and reporting formats as recommended by the International Conference on Harmonisation and to define new terms; to add to or revise current reporting requirements; to revise certain reporting time frames; and to propose other revisions to these regulations to enhance the quality of safety reports received by FDA.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 03/14/03 | 68 FR 12406 |
| NPRM Comment Period Extended | 06/18/03 | |
| NPRM Comment Period End | 07/14/03 | |
| NPRM Comment Period Extension End | 10/14/03 | |
| Final Action | 07/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AA97

### 330. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS

**Regulatory Plan:** This entry is Seq. No. 43 in part II of this issue of the **Federal Register**.

**RIN:** 0910–AB88

### 331. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

**Regulatory Plan:** This entry is Seq. No. 44 in part II of this issue of the **Federal Register**.

**RIN:** 0910–AC14

### 332. TOLL–FREE NUMBER FOR REPORTING ADVERSE EVENTS ON LABELING FOR HUMAN DRUGS

**Legal Authority:** 21 USC 355b

**Abstract:** To require the labeling of human drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act to include a toll-free number for reports of adverse events, and a statement that the number is to be used for reporting purposes only and not to receive medical advice.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 04/22/04 | 69 FR 21778 |
| NPRM Comment Period End | 07/21/04 | |
| Final Action | 01/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AC35

### 333. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES

**Legal Authority:** PL 105–115, sec 121

**Abstract:** Section 121 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) directs FDA to establish requirements for current good manufacturing practices (CGMPs) for positron emission tomography (PET) drugs, a type of radiopharmaceutical. The proposed rule would adopt CGMPs that reflect the unique characteristics of PET drugs.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 09/20/05 | 70 FR 55038 |
| NPRM Comment Period End | 12/19/05 | |
| Final Action | 04/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AC55

### 334. COCHINEAL EXTRACT AND CARMINE LABEL DECLARATION

**Legal Authority:** 21 USC 379e(b)

**Abstract:** The Agency published a proposed rule on January 30, 2006, to require the label declaration of all foods and cosmetics containing the color additives cochineal extract and carmine in order to protect consumers with allergies to these additives. This proposal was issued in response to adverse event reports received by FDA and to a citizen petition submitted to FDA. The comment period ended on May 1, 2006. FDA intends to issue a final rule after reviewing comments.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 01/30/06 | 71 FR 4839 |
| NPRM Comment Period End | 05/01/06 | |
| Final Action | 05/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF12

### 335. CHARGING FOR INVESTIGATIONAL DRUGS

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371; 42 USC 262

**Abstract:** On December 14, 2006, (71 FR 75168), FDA published a proposed rule to amend FDA's investigational new drug regulation concerning charging for investigational drugs. The rule will clarify the circumstances in which charging for an investigational drug in a clinical trial is appropriate, set forth criteria for charging for an investigational drug for the different types of treatment uses described in the Agency's rule on expanded access to investigational drugs for treatment use, and clarify what costs can be recovered for an investigational drug. The rule is intended to permit charging for a broader range of investigational uses than is explicitly permitted in current regulations.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 12/14/06 | 71 FR 75168 |
| NPRM Comment Period End | 03/14/07 | |
| Final Action | 09/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF13

### 336. EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE

**Regulatory Plan:** This entry is Seq. No. 46 in part II of this issue of the **Federal Register**.

**RIN:** 0910–AF14

### 337. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (ANTIHISTAMINE) PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling claims for the common cold.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| Final Action (Amendment) (Common Cold) | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF31

### 338. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (BRONCHODILATOR) PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling for these products.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM (Amendment – Ephedrine Single Ingredient) | 07/13/05 | 70 FR 40237 |
| Final Action (Technical Amendment) | 03/19/07 | 72 FR 12370 |
| Final Action (Amendment – Ephedrine Single Ingredient) | 06/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF32

### 339. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (COMBINATION) PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The technical amendment revises a paragraph designation in the CFR. The other action finalizes cough/cold combination products containing oral bronchdilators and expectorants.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM (Amendment) | 07/13/05 | 70 FR 40232 |
| Final Action (Technical Amendment) | 12/00/07 | |
| Final Action | 06/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF33

### 340. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (NASAL DECONGESTANT) PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the ingredient phenyl propanolamine.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM (Amendment) (Sinusitis Claim) | 08/02/04 | 69 FR 46119 |
| NPRM (Phenylephrine Bitartrate) | 11/02/04 | 69 FR 63482 |
| NPRM (Phenyl propanolamine) | 12/22/05 | 70 FR 75988 |
| Final Action (Amendment) (Sinusitis Claim) | 10/31/05 | 70 FR 58974 |
| Final Action (Phenylephrine Bitartrate) | 08/01/06 | 71 FR 83358 |
| Final Action (Phenyl propanolamine) | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF34

### 341. OVER–THE–COUNTER (OTC) DRUG REVIEW—LABELING OF DRUG PRODUCTS FOR OTC HUMAN USE

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 371; 21 UCS 374; 21 USC 379e

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling for convenience (small) size OTC drug packages.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM (Convenience Sizes) | 12/12/06 | 71 FR 74474 |
| Final Action | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF37

### 342. OVER–THE–COUNTER (OTC) DRUG REVIEW—LAXATIVE DRUG PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action will address laxative drug products. The other action will address psyllium laxative drug products in a granular dosage form.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| Final Action (Granular Psyllium) | 03/29/07 | 72 FR 14669 |
| Final Action (Laxative Drug Products) | 06/00/08 | |
| NPRM (Professional Labeling) | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF38

### 343. OVER–THE–COUNTER (OTC) DRUG REVIEW—SKIN PROTECTANT PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses labeling for products formulated and marketed as lip protectants. The second action addresses skin protectant products used to treat fever blisters and cold sores. The third action identifies safe and effective skin protectant active ingredients to treat and prevent diaper rash. The fourth action addresses astringent active ingredients.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| Final Action (Technical Amendments) | 12/00/07 | |
| Final Action (Fever Blisters/Cold Sores) | 12/00/08 | |
| Final Action (Diaper Rash) | 12/00/08 | |
| Final Action (Aluminum Acetate) (Technical Amendment) | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF42

### 344. OVER–THE–COUNTER (OTC) DRUG REVIEW—VAGINAL CONTRACEPTIVE PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360a; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 371a; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action will address labeling warning statements for products containing Nonoxynol 9. The other action addresses vaginal contraceptive drug products.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM (Vaginal Contraceptive Drug Products) | 06/00/08 | |
| Final Action (Warnings) | 12/00/07 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF44

### 345. OVER–THE–COUNTER (OTC) DRUG REVIEW—WEIGHT CONTROL PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action addresses the ingredient phenylpropanolamine, and the other action addresses the ingredient benzocaine.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM (Phenyl propanolamine) | 12/22/05 | 70 FR 75988 |
| NPRM (Benzocaine) | 12/00/08 | |
| Final Action (Phenyl propanolamine) | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF45

### 346. SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED TO PREVENT THE TRANSMISSION OF BOVINE SPONGIFORM ENCEPHALOPATHY

**Legal Authority:** 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

**HHS—FDA** **Final Rule Stage**

**Abstract:** On October 6, 2005, the Food and Drug Administration (FDA) proposed to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals to help strengthen existing safeguards to prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. The discovery of a BSE-positive dairy cow in December 2003 has caused FDA to review its policies for prevention of BSE, which resulted in this rulemaking.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| ANPRM | 07/14/04 | 69 FR 42288 |
| ANPRM Comment Period End | 08/13/04 | |
| NPRM | 10/06/05 | 70 FR 58569 |
| NPRM Comment Period End | 12/20/05 | |
| Final Action | 03/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF46

### 347. OVER–THE–COUNTER (OTC) DRUG REVIEW—ANTACID PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action addresses the labeling of products containing sodium bicarbonate as an active ingredient. The other action addresses the use of antacids to relieve upset stomach associated with overindulgence in food and drink.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| Final Action (Sodium Bicarbonate Labeling) | 06/00/08 | |
| Final Action (Overindulgence Labeling) | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF52

### 348. OVER–THE–COUNTER (OTC) DRUG REVIEW—SKIN BLEACHING PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses skin bleaching drug products containing hydroquinone.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 08/29/06 | 71 FR 51146 |
| NPRM Comment Period End | 12/27/06 | |
| Final Action | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF53

**Department of Health and Human Services (HHS)**
**Food and Drug Administration (FDA)** **Long-Term Actions**

### 349. REQUIREMENTS FOR SUBMISSION OF IN VIVO BIOEQUIVALENCE DATA

**Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 355a; 21 USC 356; 21 USC 356a to 356c; 21 USC 371; 21 USC 374; 21 USC 379

**Abstract:** The Food and Drug Administration (FDA) published a proposed regulation on October 29, 2003 (68 FR 61640), that would amend its regulations on submission of bioequivalence (BE) data to require an abbreviated new drug application (ANDA) applicant to submit data from all BE studies the applicant conducts on a drug product formulation submitted for approval. In the past, ANDA applicants have submitted BE studies demonstrating that a generic product meets BE criteria for FDA to approve the ANDA but have not typically submitted additional BE studies conducted on the same drug product formulation. If finalized, this rule would require ANDA applicants to submit information, in either a complete or summary report, from all additional passing and nonpassing BE studies conducted on the same drug product formulation submitted for approval.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 10/29/03 | 68 FR 61640 |
| Final Action | To Be | Determined |

**Regulatory Flexibility Analysis Required:** Yes

**Agency Contact:** Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Suite 1101,

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**RIN:** 0910–AC23

### 350. HEALTH CLAIMS

**Legal Authority:** 21 USC 343; 21 USC 371

**Abstract:** On November 25, 2003 (68 FR 66040), FDA issued an advance notice of proposed rulemaking (ANPRM) to request comments on alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements. FDA also solicited comments on various other issues related to health claims and on the appropriateness and nature of dietary guidance statements on conventional food and dietary supplement labels. This ANPRM was signaled in the July 11, 2003 (68 FR 41387), notice that announced the availability of the final report of the FDA Task Force on the Consumer Health Information for Better Nutrition Initiative.

Comments on the regulatory alternatives and additional topics identified in the ANPRM will inform FDA decisions about regulation of qualified health claims.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| ANPRM | 11/25/03 | 68 FR 66040 |
| ANPRM Comment Period Extended | 01/27/04 | 69 FR 3868 |
| ANPRM Comment Period End | 02/25/04 | |
| NPRM | To Be Determined | |

**Regulatory Flexibility Analysis Required:** Yes

**Agency Contact:** Julie Moss, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–830), 5100 Paint Branch Parkway, College Park, MD 20740
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**RIN:** 0910–AF09

### 351. OVER–THE–COUNTER (OTC) DRUG REVIEW—OPHTHALMIC PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses emergency first aid eyewash products.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM (Amendment) (Emergency First Aid Eyewashes) | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

**Agency Contact:** Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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**RIN:** 0910–AF39

### 352. OVER–THE–COUNTER (OTC) DRUG REVIEW—OVERINDULGENCE IN FOOD AND DRINK PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses products containing bismuth subsalicylate for relief of symptoms of upset stomach due to overindulgence resulting from food and drink.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM (Amendment) | 01/05/05 | 70 FR 741 |
| Final Action | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

**Agency Contact:** Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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**RIN:** 0910–AF51

### 353. OVER–THE–COUNTER (OTC) DRUG REVIEW—STIMULANT DRUG PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the use of stimulant active ingredients to relieve symptoms associated with a hangover.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM (Amendment) (Hangover) | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

**Agency Contact:** Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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**RIN:** 0910–AF56

### 354. OVER–THE–COUNTER ANTIDIARRHEAL DRUG PRODUCTS

**Legal Authority:** 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a

**Abstract:** The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses products containing antidiarrheal drug ingredients.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 12/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0910–AF63

### 355. FOOD LABELING; SERVING SIZES; REFERENCE AMOUNT FOR BAKING POWDER, BAKING SODA, AND PECTIN (SECTION 610 REVIEW)

**Legal Authority:** 15 USC 1453; 15 USC 1454; 15 USC 1455; 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

**Abstract:** Section 101.9 (21 CFR part 101.9) describes the nutrition labeling regulations for the reference amount customarily consumed per eating occasion for the food category ''Baking powder, baking soda, pectin.'' Section 101.12 (21 CFR part 101.12) includes 1/8 teaspoon (tsp) as an additional allowable household measure. FDA is undertaking a review of sections 101.9 and 101.12 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in sections 101.9 and 101.12 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for the regulations in sections 101.9 and 101.12; (2) the nature of complaints or comments received concerning the regulations in sections 101.9 and 101.12; (3) the complexity of the regulations; (4) the extent to which the regulations in sections 101.9 and 101.12 overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in sections 101.9 and 101.12.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| Begin Review | 12/00/08 | |
| End Review | 03/00/09 | |

**Regulatory Flexibility Analysis Required:** Undetermined

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**RIN:** 0910–AF99

## Department of Health and Human Services (HHS)
## Food and Drug Administration (FDA)



### 356. MEDICAL DEVICES; CURRENT GOOD MANUFACTURING PRACTICE (CGMP) FINAL RULE; QUALITY SYSTEMS REGULATIONS (COMPLETION OF A SECTION 610 REVIEW)

**Legal Authority:** 5 USC 610

**Abstract:** FDA has undertaking a review of part 820 under section 610 of the Regulatory Flexibility Act. The agency did not receive any comments during the review process of part 820 under section 610 review, therefore the regulation will continue without change. The purpose of the review was to determine whether the regulations in part 820 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on substantial number of small entities. FDA has solicited comments on, the following (1) the continued need for the regulation in part 820; (2) the nature of complaints or comments received concerning the regulation in part 820; (3) the complexity of the regulation in part 820; (4) the extent to which the regulation in part 820 overlap, duplicate, or conflict with other Federal, State, or governmental rules: and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation in part 820.

The section 610 review has been carried out along with a regulation review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the agency's regulatory program more effective in achieving its goals, less burdensome, or in greater alignment with the President's priorities and the principles set forth in the Executive order. The combined effect of the two reviews will be to determine if it is possible to redesign current good manufacturing practices in ways that will maintain or increase the effectiveness of preventive and sanitary controls, and, at the same time, reduce compliance and other costs associated with the regulations.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| Begin Review of Current Regulation | 01/05/06 | |
| End Review | 07/31/07 | |

**Regulatory Flexibility Analysis Required:** No

**Agency Contact:** Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ–215), PI50 RM150F, 1350 Piccard Drive, Rockville, MD 20850
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**RIN:** 0910–AF71

### 357. PACKAGE SIZE LIMITATION FOR SODIUM PHOSPHATES ORAL SOLUTION AND WARNING AND DIRECTION STATEMENTS FOR ORAL AND RECTAL SODIUM PHOSPHATES FOR OVER–THE–COUNTER LAXATIVE USE (SECTION 610 REVIEW)

**Legal Authority:** 5 USC 610

**Abstract:** Section 201.307 (21 CFR sec. 201.307) describes a final rule to limit the container size for sodium phosphates oral solution (dibasic sodium phosphate/monobasic sodium phosphate oral solution) to not greater than 90 milliliters (mL) (3 ounces (oz) when used as an over-the-counter (OTC) laxative drug product. FDA limited the container size due to reports of deaths associated with an overdosage of sodium phosphates when packaged in a larger size container and a larger-than-intended dose was ingested inadvertently. In addition, this final rule required warning and direction statements to inform consumers that exceeding the recommended dose of oral and rectal sodium phosphates products in a 24-hour period could be harmful.

FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in section 201.307. The purpose of this review is to determine whether the regulation in section 201.307 should be continued without change, or whether it should be further amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for the regulation in section 201.307; (2) the nature of the complaints or comments received concerning the regulation in section 201.307; (3) the complexity of the regulation in section 201.307; (4) the extent to which the regulation in section 201.307 overlaps, duplicates, or conflicts with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed for the products still subject to the package size and labeling regulation in section 201.307.

The section 610 review has been carried out along with a regulatory review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the Agency's regulatory program more effective in achieving its goals, less burdensome, or in greater alignment with the President's priorities and the principles set forth in the Executive order. During the review, FDA received one comment. This comment will be addressed on a future rulemaking.

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| End Review | 09/04/07 | |

**Regulatory Flexibility Analysis Required:** No

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**RIN:** 0910–AF73

### 358. OVER–THE–COUNTER DRUG PRODUCTS CONTAINING ANALGESIC/ANTIPYRETIC ACTIVE INGREDIENTS FOR INTERNAL USE: REQUIRED ALCOHOL WARNING (SECTION 610 REVIEW)

**Legal Authority:** 5 USC 610

**Abstract:** Section 201.322 describes a regulation that requires an alcohol warning for all over-the-counter (OTC) drug products, labeled for adult use, containing internal analgesic/antipyretic active ingredients. The required warning statements advise consumers with a history of heavy alcohol use to consult a physician for advice about the use of OTC internal analgesic/antipyretic drug products. FDA issued the final rule after considering comments on the Agency's proposed regulation for OTC internal analgesic, antipyretic, and antirheumatic drug products: A proposed regulation to establish an alcohol warning, recommendations from its Nonprescription Drugs Advisory Committee (NDAC) and Arthritis Drugs Advisory Committee (ADAC), and data submitted to the agency.

FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in section 201.322. The purpose of this review is to determine whether the regulation in section 201.322 should be continued without change, or whether it should be further amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA proposed to remove section 201.322 in the Federal Register on December 26, 2006 (71 FR 77314). FDA will consider the comments received in response to that proposal and, in addition, is soliciting comments on the following: (1) The continued need for the regulation in section 201.322; (2) the nature of the complaints or comments received concerning the regulation in section 201.322; (3) the complexity of the regulation in section 201.322; (4) the extent to which the regulation in section 201.322 overlaps, duplicates, or conflicts with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed for the products still subject to the labeling regulation in section 201.322.

The section 610 review has been carried out along with a regulatory review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the Agency's regulatory program more effective in achieving its goals, less burdensome, or in greater alignment with the President's priorities and the principles set forth in the Executive order. This review concluded with the publication of proposed amendment of the tentative final monograph; required warnings and other labeling. 71 FR 77314

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| End Review | 12/26/06 | |

**Regulatory Flexibility Analysis Required:** No

**Agency Contact:** Walter Jefferson Ellenberg

**HHS—FDA** **Completed Actions**

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**RIN:** 0910–AF74

## Department of Health and Human Services (HHS) — Proposed Rule Stage
## Centers for Medicare & Medicaid Services (CMS)

### 359. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (COPS) (CMS–3819–P) (SECTION 610 REVIEW)

**Legal Authority:** 42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bb

**Abstract:** This proposed rule would revise the existing Conditions of Participation (CoPs) that Home Health Agencies (HHAs) must meet to participate in the Medicare program. The requirements focus on the actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our efforts to achieve broad-based improvements and measurements of the quality of care furnished through Federal programs while at the same time reducing procedural burdens on providers.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 03/10/97 | 62 FR 11005 |
| NPRM Comment Period End | 06/09/97 | |
| Second NPRM | 02/00/08 | |

**Regulatory Flexibility Analysis Required:** No

**Agency Contact:** Commander Mercedes Benitez–McCrary, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–05–14, 7500 Security Boulevard, Baltimore, MD 21244
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**RIN:** 0938–AG81

### 360. REVISIONS TO HIPAA CODE SETS (CMS–0013–P)

**Legal Authority:** PL 104–191

**Abstract:** This proposed rule would revise some of the adopted transaction and code set standards detailed in regulations published by HHS on August 17, 2000, and February 20, 2003.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 01/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

**Agency Contact:** Denise Buenning, Health Insurance Specialist, Office of E–Health Standards and Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244
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**RIN:** 0938–AN25

### 361. HOME AND COMMUNITY–BASED SERVICES (HCBS) STATE PLAN OPTION (CMS–2249–P)

**Legal Authority:** Deficit Reduction Act of 2005; PL 109–171, sec 6086

**Abstract:** This proposed rule would amend the Medicaid regulations to define and describe the home and community-based State plan services implementing new section 1915(i) of the Social Security Act as added by section 6086 of the Deficit Reduction Act of 2005.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 03/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

**Agency Contact:** Theresa Pratt, Director, Division of Integrated Health Systems, Disabled and Elderly Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid State Operations, Mailstop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244
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**RIN:** 0938–AO53

### 362. PROSPECTIVE PAYMENT SYSTEM FOR LONG–TERM CARE HOSPITALS RY 2009: ANNUAL PAYMENT RATE UPDATES (CMS–1393–P)

**Legal Authority:** sec 123 PL 106–113; sec 307(b) PL 106–554

**Abstract:** This major rule proposes changes to the Medicare long-term care hospitals (LTCH) prospective payment system (PPS) annual updates the payment rates for rate year (RY) 2009.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 01/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

**Agency Contact:** Judith Richter, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–16–07, 7500 Security Boulevard, Baltimore
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**RIN:** 0938–AO94

### 363. • ESTABLISHING ADDITIONAL MEDICARE PROVIDER AND SUPPLIER ENROLLMENT SAFEGUARDS (CMS–6045–P)

**Legal Authority:** sec. 4312(a) of BBA of 1997

**Abstract:** This proposed rule would expand existing provider and supplier enrollment requirements to obtain or maintain Medicare billing privileges.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 02/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

## HHS—CMS — Proposed Rule Stage

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**RIN:** 0938–AP01

### 364. ● HOSPICE WAGE INDEX FOR FY 2009 (CMS–1548–P)

**Legal Authority:** 42 USC 1814(i)(1) and 1814(i)(2)

**Abstract:** This rule proposes the annual update to the hospice wage index for FY 2009. The wage index is used to reflect local differences in wage levels. The hospice wage index methodology and values are based on recommendations of a negotiated rulemaking advisory committee and were originally published on August 8, 1997.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 04/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

**Agency Contact:** Terri Deutsch, Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C5–08–18, 7500 Security Boulevard, Baltimore, MD 21244
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**RIN:** 0938–AP14

### 365. ● CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FY 2009 RATES (CMS–1390–P)

**Legal Authority:** sec 1886(b) of the Social Security Act

**Abstract:** This major rule proposes to revise the Medicare hospital Inpatient Prospective Payment Systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems. Under section 106(b)(2) of the Tax Relief and Health Care Act of 2006, this rule also proposes to revise the wage index adjustment under the hospital IPPS.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 04/00/08 | |

**Regulatory Flexibility Analysis Required:** Yes

**Agency Contact:** Marc Hartstein, Deputy Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–25–11, 7500 Security Boulevard, Baltimore, MD 21244
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**RIN:** 0938–AP15

### 366. ● CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM FOR CY 2009 (CMS–1404–P)

**Regulatory Plan:** This entry is Seq. No. 50 in part II of this issue of the **Federal Register**.

**RIN:** 0938–AP17

## Department of Health and Human Services (HHS) / Centers for Medicare & Medicaid Services (CMS) — Final Rule Stage

### 367. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS–3818–F) (SECTION 610 REVIEW)

**Regulatory Plan:** This entry is Seq. No. 52 in part II of this issue of the **Federal Register**.

**RIN:** 0938–AG82

### 368. HOSPICE CARE CONDITIONS OF PARTICIPATION (CMS–3844–F) (SECTION 610 REVIEW)

**Regulatory Plan:** This entry is Seq. No. 53 in part II of this issue of the **Federal Register**.

**RIN:** 0938–AH27

## Department of Health and Human Services (HHS) / Centers for Medicare & Medicaid Services (CMS) — Long-Term Actions

### 369. HOSPITAL CONDITIONS OF PARTICIPATION: LABORATORY SERVICES (CMS–3014–F) (SECTION 610 REVIEW)

**Legal Authority:** 42 USC 1302; 42 USC 1395hh

**Abstract:** This rule requires hospitals that transfuse blood and blood components to prepare and follow written procedures for appropriate action when it is determined that blood and blood products the hospital received and transfused are at increased risk for transmitting hepatitis C virus (HCV); quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and maintain records for at least 10 years.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 11/16/00 | 65 FR 69416 |
| Interim Final Rule | 08/24/07 | 72 FR 48562 |
| Interim Final Rule Comment Period End | 10/23/07 | |
| Final Action | 08/00/10 | |

**Regulatory Flexibility Analysis Required:** No

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**RIN:** 0938–AJ29

### 370. SURETY BOND REQUIREMENT FOR SUPPLIERS OF DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) (CMS–6006–F)

**Legal Authority:** sec 4312(a) of BBA of 1997

**Abstract:** This rule implements section 4312(a) of the Balanced Budget Act of 1997, which requires a Medicare supplier of durable medical equipment (DME) to furnish CMS with a surety bond.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 08/01/07 | 72 FR 42001 |
| NPRM Comment Period End | 10/01/07 | |
| Final Action | 08/00/10 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AO84

### 371. • MEDICAID GRADUATE MEDICAL EDUCATION (CMS–2279–F) (SECTION 610 REVIEW)

**Legal Authority:** tTitle XIX; Social Security Act

**Abstract:** As part of the President's 2008 Budget, this major rule establishes that States may not include GME as a reimbursable cost or program under their approved Medicaid State Plan. The rule enhances fiscal integrity and improves accountability with respect to payment for medical services in the Medicaid program.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 05/23/07 | 72 FR 28930 |
| NPRM Comment Period End | 06/22/07 | |
| Final Action | 11/00/08 | |

**Regulatory Flexibility Analysis Required:** No

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**RIN:** 0938–AO95

## Department of Health and Human Services (HHS)
## Centers for Medicare & Medicaid Services (CMS)



### 372. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS (CMS–1810–F)

**Legal Authority:** 42 USC 1877

**Abstract:** This final rule is the third phase (Phase III) of a final rulemaking amending our regulations regarding the physician self-referral prohibition in section 1877 of the Social Security Act (the Act). Specifically, this rule finalizes and responds to public comments regarding the Phase II interim final rule with commment period published on March 26, 2004. Phase II set forth the self-referral prohibition and applicable definitions, interpreted various statutory exceptions to the prohibition, and created additional regulatory exceptions for arrangements that do not pose a risk of program or patient abuse (69 FR 16054). In response to public comments in Phase III final rule, we have reduced the regulatory burden on the health care industry through the interpretation of statutory exceptions and by modifying the exceptions that were created using the Secretary's discretionary authority under section 1877(b)(4) of the Act to promulgate exceptions for financial relationships that pose no risk of program or patient abuse.

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| Final Action | 09/05/07 | 72 FR 51012 |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AK67

### 373. COMPETITIVE ACQUISITION FOR CERTAIN DURABLE MEDICAL EQUIPMENT (DME), PROSTHETICS, ORTHOTICS, AND SUPPLIES (CMS–1270–F)

**Legal Authority:** PL 108–173, MMA; Deficit Reduction Act of 2005, PL 109–171, sec 5101

**Abstract:** Section 302 of the Medicare Modernization Act establishes DME competitive bidding. National competitive bidding will provide a program for using market forces to set Medicare payment amounts. This will create incentives for suppliers to provide quality items and services while at the same time providing Medicare with reasonable prices for payment. This rule also incorporates provisions from section 5105 of the DRA of 2005, which concerns beneficiary ownership of certain DMEs.

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| Notice | 04/10/07 | 72 FR 16794 |
| Final Action | 04/11/07 | 72 FR 17002 |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AN14

### 374. MEDICARE PART B COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS (CMS–1325–F)

**Legal Authority:** MMA of 2003, sec 303(d)

**Abstract:** Section 303(d) of the Medicare Modernization Act requires the implementation of a competitive bidding program for Medicare Part B drugs not paid on a cost or prospective payment system basis. Beginning July 1, 2006, physicians will be given a choice between purchasing these drugs and being paid by Medicare under the average sales price (ASP) system, or obtaining these drugs from vendors selected in a competitive bidding process. If the physician elects to obtain drugs from a competitive vendor, the vendor will bill Medicare for the drug.

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| Withdrawn | 08/08/07 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AN58

### 375. MEDICAID PRESCRIPTION DRUGS—AVERAGE MANUFACTURER PRICE (CMS–2238–FC)

**Legal Authority:** 42 USC 1396r.8; Deficit Reduction Act of 2005, PL 109–171, sec 6001 to 6003

**Abstract:** This final rule implements sections 6001, 6002, and 6003 of the Deficit Reduction Act of 2005. This rule sets the Federal upper reimbursement limit (FUL) as 250 percent of the average manufacturer price (AMP) for drugs on the FUL list, and will clarify the requirements and manner in which AMPs are determined for multiple-source drugs and other drug payment revisions. This rule also lists the physician administered multiple-source drugs that the Secretary determines have the highest dollar volume of dispensing in Medicaid and will require manufacturers to include authorized generics when they report their AMP and best price for covered outpatient drugs to the Secretary.

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| Final Action | 07/17/07 | 72 FR 39142 |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AO20

### 376. PROSPECTIVE PAYMENT SYSTEM FOR LONG–TERM CARE HOSPITALS RY 2008: ANNUAL PAYMENT RATE UPDATES AND POLICY CHANGES (CMS–1529–F)

**Legal Authority:** PL 106–113, sec 123 ; PL 106–554, sec 307(b)

**Abstract:** This rule finalizes the annual payment rate update for the Rate Year (RY) 2008 prospective payment system for Medicare long-term care hospitals and also presents proposed changes or revisions on LTCH PPS policy for public comment.

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| Final Action | 05/11/07 | 72 FR 26870 |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AO30

### 377. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM REFINEMENTS AND RATE UPDATE FOR CALENDAR YEAR 2008 (CMS–1541–F)

**Legal Authority:** Social Security Act, sec 1102 and 1871; (42 USC 1302 and 1395 (hh))

**Abstract:** This rule, CMS-1541-F, estimates the net impact, including a 2.75 percent reduction to the case-mix weights to account for nominal increase in case-mix, to be approximately $20 million in CY 2008 expenditures. That estimate incorporates the 3.0 percent home health market basket increase (an estimated additional $430 million in CY 2008 expenditures attributable only to the CY 2008 home health market basket update), and the 2.75 percent decrease (-$410 million for the first year of a 3-year phase in) to the HH PPS national standardized 60-day episode rate to account for the nominal increase in case-mix under the HH PPS.

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| NPRM | 05/04/07 | 72 FR 25356 |
| Final Action | 08/29/07 | 72 FR 49761 |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AO32

### 378. COST LIMITS FOR GOVERNMENTALLY–OPERATED PROVIDERS (CMS–2258–FC) (COMPLETION OF A SECTION 610 REVIEW)

**Legal Authority:** sec 1102 of the Social Security Act (42 USC 1302)

**Abstract:** The final rule with comment will: (1) Clarify that only units of government are able to participate in the financing of the non-Federal share; (2) establish minimum requirements for documenting cost when using a certified public expenditure; (3) limit providers operated by units of government to reimbursement that does not exceed the cost of providing covered services to eligible Medicaid recipients; and (4) establish a new regulatory provision explicitly requiring that provders receive and retain the total computable amount of their Medicaid payments.

**Timetable:**

| Action | Date | FR Cite |
|---|---|---|
| NPRM | 01/18/07 | 72 FR 2236 |
| NPRM Comment Period End | 03/19/07 | |
| Final Action | 05/29/07 | 72 FR 29748 |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AO57

**HHS—CMS** **Completed Actions**

### 379. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION FACILITIES FOR FY 2008 (CMS–1551–F)

**Legal Authority:** SSA, sec 1886(i); PL 105–33; PL 106–554; PL 106–113

**Abstract:** This rule updates rates for the prospective payment system for inpatient rehabilitation facilities for FY 2008.

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| NPRM | 05/08/07 | 72 FR 26230 |
| Final Action | 08/07/07 | 72 FR 44283 |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AO63

### 380. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2008 (CMS–1545–F)

**Legal Authority:** Social Security Act, sec 1888(e)

**Abstract:** This proposed rule updates the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs), for fiscal year (FY) 2008. In addition, this rule revises and rebase the SNF market basket.

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| NPRM | 05/04/07 | 72 FR 25526 |
| Final Action | 08/03/07 | 72 FR 43412 |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AO64

### 381. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FY 2008 RATES (CMS–1533–FC)

**Legal Authority:** sec 1886(d) of the Social Security Act

**Abstract:** This rule proposes to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems.

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| NPRM | 05/03/07 | 72 FR 24680 |
| Final Action | 08/22/07 | 72 FR 47130 |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AO70

### 382. HOSPICE WAGE INDEX FOR FY 2008 (CMS–1539–F)

**Legal Authority:** 42 USC 1814(i)(1) and 1814(i)(2)

**Abstract:** This rule updates the hospice wage index for FY 2008. The wage index is used to reflect local differences in wage levels. The hospice wage index methodology and values are based on recommendations of a negotiated rulemaking advisory committee and were originally published on August 8, 1997.

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| NPRM | 05/01/07 | 72 FR 24116 |
| Final Action | 08/31/07 | 72 FR 50214 |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AO72

### 383. REVISED PAYMENT SYSTEM FOR SERVICES FURNISHED IN AMBULATORY SURGICAL CENTERS (ASCS) EFFECTIVE JANUARY 1, 2008 (CMS–1517–F)

**Legal Authority:** 42 USC 1833(i)(2)(D)(iii)

**Abstract:** This rule revises the method by which Medicare sets payment rates for ASC facility services and includes illustrative new payment rates for ASC services in accordance with that methodology. This rule finalizes policies proposed as part of the August 23, 2006, CY 2007 Outpatient Prospective Payment System rule.

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| Final Action | 08/02/07 | 72 FR 42470 |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AO73

### 384. FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES—UPDATE FOR CY 2008 (CMS–1552–N)

**Legal Authority:** sec 1834 (e) of the Social Security Act

**Abstract:** This notice updates the fee schedule for ambulance services under the Medicare program, implementing section 1834(e) of the Social Security Act (effective January 1, 2008).

**Completed:**

| Reason | Date | FR Cite |
|---|---|---|
| Withdrawn | 08/08/07 | |

**Regulatory Flexibility Analysis Required:** Yes

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**RIN:** 0938–AO85

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