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Part V

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 that inventories of rulemaking actions under development within the Department be made available to the public semiannually. The purpose of these requirements 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 to the Department, Department of Health and Human Services, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: The capsulized information provided in the Agenda sets out information rulemaking activities in which the Department is currently engaged. 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.

Please note that the summaries included below relate only to those rulemakings that are likely to have significant economic impact on a substantial number of small entities; the Regulatory Flexibility Act requires publication of this information in the **Federal Register.** The complete Agenda is now accessible online at www.reginfo.gov, where rapid electronic access to information about the full range of HHS rulemakings is available.

The Department welcomes the views of all concerned with regard to planned rulemakings. Comments may be directed to the agency officials cited in each of the summaries. 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: March 27, 2008.

Ann C. Agnew,

Executive Secretary to the Department.

Substance Abuse and Mental Health Services Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
125	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
126	Control of Communicable Diseases, Interstate and Foreign Quarantine	0920–AA12

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
127	Food Labeling; Serving Sizes; Reference Amount for Baking Powder, Baking Soda, and Pectin **(Section 610 Review)**	0910–AF99
128	Biological Products; Reporting of Biological Product Deviations in Manufacturing **(Section 610 Review)**	0910–AG05

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
129	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics	0910–AC52
130	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910–AF11
131	Over-the-Counter (OTC) Drug Review—Stimulant Drug Products	0910–AF56
132	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61

HHS

Food and Drug Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
133	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
134	Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
135	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements	0910–AB88
136	Prevention of Salmonella Enteritidis in Shell Eggs	0910–AC14
137	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910–AC35
138	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
139	Cochineal Extract and Carmine Label Declaration	0910–AF12
140	Charging for Investigational Drugs	0910–AF13
141	Expanded Access to Investigational Drugs for Treatment Use	0910–AF14
142	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
143	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
144	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
145	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
146	Substances Prohibited From Use in Animal Food or Feed To Prevent the Transmission of Bovine Spongiform Encephalopathy	0910–AF46
147	Over-the-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products	0910–AF51
148	Over-the-Counter (OTC) Drug Review—Antacid Products	0910–AF52

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
149	Requirements for Submission of In Vivo Bioequivalence Data	0910–AC23
150	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
151	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
152	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
153	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
154	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
155	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40
156	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
157	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
158	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44
159	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
160	Over-the-Counter (OTC) Drug Review—Skin Bleaching Products	0910–AF53
161	Over-the-Counter Antidiarrheal Drug Products	0910–AF63
162	Over-the-Counter (OTC) Drug Review—Poison Treatment Drug Products	0910–AF68
163	Over-the-Counter (OTC) Drug Review—Urinary Analgesic Drug Products	0910–AF70
164	Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution **(Section 610 Review)**	0910–AG06
165	Process Controls for Animal Feed Ingredients and Mixed Animal Feed	0910–AG10

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
166	Health Claims	0910–AF09

HHS

Food and Drug Administration—Completed Actions (Continued)

Sequence Number	Title	Regulation Identifier Number
167	Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients **(Completion of a Section 610 Review)**	0910–AF75
168	Medical Devices: Classification/Reclassification; Restricted Devices; Analyte Specific Reagents **(Completion of a Section 610 Review)**	0910–AF76
169	Natural Rubber-Containing Medical Device; User Labeling **(Completion of a Section 610 Review)**	0910–AF77
170	Financial Disclosure by Clinical Investigators **(Completion of a Section 610 Review)**	0910–AF79
171	Beverages: Bottled Water **(Completion of a Section 610 Review)**	0910–AF80
172	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 **(Completion of a Section 610 Review)**	0910–AF83

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
173	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P) **(Section 610 Review)**	0938–AG81
174	Revisions to HIPAA Code Sets (CMS-0013-P) **(Section 610 Review)**	0938–AN25
175	Home and Community-Based Services (HCBS) State Plan Option (CMS-2249-F) **(Section 610 Review)**	0938–AO53
176	Hospice Wage Index for FY 2009 (CMS-1548-P)	0938–AP14
177	Changes to the Hospital Inpatient Prospective Payment Systems and FY 2009 Rates (CMS-1390-P)	0938–AP15
178	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2009 (CMS-1404-P)	0938–AP17
179	Requirements for Long Term Care Facilities: Hospice Services (CMS-3140-P) **(Section 610 Review)**	0938–AP32

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
180	Medicare and Medicaid Programs; Hospice Care Conditions of Participation (CMS-3844-F) **(Section 610 Review)**	0938–AH27
181	Inpatient Psychiatric Facility Prospective Payment System—Update for Rate Year Beginning July 1, 2008 (RY 2009) (CMS-1401-N)	0938–AO92
182	Prospective Payment System for Long-Term Care Hospitals RY 2009: Annual Payment Rate Updates (CMS-1393-F)	0938–AO94
183	Changes to Long Term Care Prospective Payment System Based on Specific Provisions in the Medicare, Medicaid, and SCHIP Extension Act of 2007 (CMS-1493-IFC)	0938–AP33

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
184	Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-6006-F) **(Section 610 Review)**	0938–AO84
185	Establishing Additional Medicare Provider and Supplier Enrollment Safeguards (CMS-6045-P) **(Section 610 Review)**	0938–AP01

HHS

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
186	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-F) **(Completion of a Section 610 Review)**	0938–AG82

Department of Health and Human Services (HHS) — Long-Term Actions
Substance Abuse and Mental Health Services Administration (SAMHSA)

125. 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	To Be Determined	

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)

126. CONTROL OF COMMUNICABLE DISEASES, INTERSTATE AND FOREIGN QUARANTINE

Legal Authority: Not Yet Determined

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. The Secretary has delegated the authority to prevent the introduction of diseases from foreign countries to the Director, CDC. CDC maintains quarantine stations at 20 ports of entry staffed with medical and public health officers who respond to reports of diseases from carriers. According to the statutory scheme, the President determines through Executive order which diseases may subject individuals to quarantine. The current disease list, which was last updated in April 2005, includes cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, severe acute respiratory syndrome (SARS), and influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic.

Timetable:

Action	Date	FR Cite
NPRM	11/30/05	70 FR 71892
Final Action	11/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Stacy Howard, Department of Health and Human Services, Centers for Disease Control and Prevention, CLFT Building 16, Room 4324, MS E03, Atlanta, GA 30329 Phone: 404 718–1056

RIN: 0920–AA12

Department of Health and Human Services (HHS) — Prerule Stage
Food and Drug Administration (FDA)

127. 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

HHS—FDA **Prerule Stage**

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

Agency Contact: Geraldine A. June, Supervisor, Product Evaluation and Labeling Team, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Brach Parkway, ONLDS (HFS–820), College Park, MD 20740
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RIN: 0910–AF99

128. • BIOLOGICAL PRODUCTS; REPORTING OF BIOLOGICAL PRODUCT DEVIATIONS IN MANUFACTURING (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 360i; 21 USC 360j; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264; 42 USC 300aa–25

Abstract: Section 600.14 (21 CFR 600.14) requires licensed manufacturers of biological products to report to FDA biological product deviations in manufacturing. Section 606.170 requires licensed manufacturers of blood and blood components including Source Plasma, unlicensed registered establishments, and transfusion services to report to FDA biological product deviations in manufacturing. Under section 610 of the Regulatory Flexibility Act, FDA is initiating a review of these regulations in parts 600 and 606 under section 610. The purpose of this review is to determine whether the regulations in parts 600 and 606 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 a substantial number of small entities. FDA will consider and is soliciting comments on the following: 1) The continued need for the regulations; 2) the nature of complaints or comments received concerning the regulations; 3) the complexity of the regulations; 4) the extent to which a regulation in parts 600 or 606 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 regulations.

Timetable:

Action	Date	FR Cite
Begin Review	05/00/08	
End Review	04/00/09	

Regulatory Flexibility Analysis Required: No

Agency Contact: Stephen M. Ripley, Team Leader, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200N (HFM–17), Rockville, MD 20852–1448
Phone: 301 827–6210

RIN: 0910–AG05

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

Proposed Rule Stage

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

Legal Authority: 21 USC 355; 21 USC 371; 42 USC 262

Abstract: The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that data submitted for NDAs, BLAs, and ANDAs, and their supplements and amendments, be provided in an electronic format that FDA can process, review, and archive. The proposal would also require that FDA periodically issue guidance on the use of standardized data structure, terminology, and code sets (e.g., the Study Data Tabulation Model (SDTM) developed by the Clinical Data Interchange Standards Consortium) to allow for more efficient and comprehensive data review.

Timetable:

Action	Date	FR Cite
NPRM	10/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Martha Nguyen, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Bldg. 51, Room 6224, Silver Spring, MD 20993–0002
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Email: martha.nguyen@fda.hhs.gov

RIN: 0910–AC52

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

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

Abstract: To amend the regulations governing the format and content of labeling for human prescription drugs and biological products (21 CFR part 201.56, 201.57, and 201.80).

Timetable:

Action	Date	FR Cite
NPRM	05/00/08	

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, 10903 New Hampshire Avenue, Bldg. 51, Room 6316, Silver Spring, MD 20993–0002
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RIN: 0910–AF11

131. 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)	04/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. 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

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

Legal Authority: 15 USC 1453 to 1455 ; 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 264

Abstract: The proposed rule would require owners or consignees to label imported food that is refused entry into the United States. The label would read, ''UNITED STATES: REFUSED ENTRY.'' The proposal would describe the label's characteristics (such as its size) and processes for verifying that the label has been affixed properly. We are taking this action to prevent the introduction of unsafe food into the United States, to facilitate the examination of imported food, and to implement section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188).

Timetable:

Action	Date	FR Cite
NPRM	07/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Philip L. Chao, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Office of Policy and Planning (HF–23), Room 14C–17, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AF61

133. 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)	To Be Determined	
Final Action (Healthcare)	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. 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–AF69

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

Food and Drug Administration (FDA)

134. 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	04/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Bldg. 51, Room 6306, Silver Spring, MD 20993–0002
Phone: 301 796–3601
Fax: 301–847–8440

RIN: 0910–AA97

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

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371; 21 USC 374; 21 USC 381; 21 USC 393; 42 USC 264

Abstract: The Food and Drug Administration published a final rule in the Federal Register of June 25, 2007 (72 FR 34752), on current good manufacturing practice (CGMP) regulations for dietary supplements. The final rule (the CGMP rule) was published to establish the minimum CGMPs necessary to ensure that, if firms engage in activities related to manufacturing, packaging, labeling, or holding dietary supplements, they do so in a manner that will ensure the quality of the dietary supplements — i.e., to ensure that the dietary supplement consistently meets the established specifications for identity, purity, strength, and composition, and limits on contaminants, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act.

FDA also published an interim final rule (IFR) in the June 25, 2007 Federal Register (72 FR 34959) that sets forth a procedure for requesting an exemption from the requirement in the final rule described above that the manufacturer conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient. This IFR allows for submission to, and review by, FDA of an alternative to the required 100 percent identity testing of components that are dietary ingredients, provided certain conditions are met. This IFR also establishes a requirement for retention of records relating to the FDA's response to an exemption request.

Timetable:

Action	Date	FR Cite
ANPRM	02/06/97	62 FR 5700
ANPRM Comment Period End	06/06/97	
NPRM	03/13/03	68 FR 12157
NPRM Comment Period End	08/11/03	
Final Action	06/25/07	72 FR 34752
Interim Final Rule	06/25/07	72 FR 34959
Interim Final Rule Comment Period End	10/24/07	
Final Action	06/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Linda Kahl, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–024), 5100 Paint Branch Parkway, College Park, MD 20740
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RIN: 0910–AB88

136. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 371; 21 USC 381; 21 USC 393; 42 USC 243; 42 USC 264; 42 USC 271;

Abstract: Publication of this final rule is an action item in the Food Protection Plan announced by the Department of Health and Human Services (HHS) in November 2007.

In July 1999, the Food and Drug Administration (FDA) and the Food Safety Inspection Service (FSIS) committed to developing an action plan to address the presence of Salmonella Enteritidis (SE) in shell eggs and egg products using a farm-to-table approach. FDA and FSIS held a public meeting on August 26, 1999, to obtain stakeholder input on the draft goals, as well as to further develop the objectives and action items for the action plan. The Egg Safety Action Plan was announced on December 11, 1999. The goal of the Action Plan is to reduce egg-related SE illnesses by 50 percent by 2005 and eliminate egg-related SE illnesses by 2010. The Egg Safety Action Plan consists of eight objectives covering all stages of the farm-to-table continuum as well as support functions. On March 30, 2000 (Columbus, OH), April 6, 2000 (Sacramento, CA), and July 31, 2000 (Washington, DC), joint public meetings were held by FDA and FSIS to solicit and discuss information related to the implementation of the objectives in the Egg Safety Action Plan.

On September 22, 2004, FDA published a proposed rule that would require egg safety measures to prevent the contamination of shell eggs with SE during egg production. The proposal also solicited comment on whether recordkeeping requirements should include a written SE prevention plan and records for compliance with the SE prevention measures, and whether safe egg handling and preparation practices should be mandated for retail establishments that specifically serve a highly susceptible population (e.g., nursing homes, hospitals, day care

centers). The proposed egg production SE prevention measures included: (1) Provisions for procurement of chicks and pullets; (2) a biosecurity program; (3) a rodent and pest control program; (4) cleaning and disinfection of poultry houses that have had an environmental or egg test positive for SE; (5) egg testing when an environmental test is positive; and (6) refrigerated storage of eggs held at the farm. Additionally, to verify that the measures have been effective, the rule proposes that producers test the poultry house environment for SE. If the environmental test is positive, eggs from that environment must be tested for SE, and if the egg test is positive, the eggs must be diverted to egg products processing or a treatment process that achieves at least a five-log destruction of SE.

The proposed rule was a step in a broader farm-to-table egg safety effort that includes FDA's requirements for safe handling statements on egg cartons, and refrigerated storage of shell eggs at retail, and egg safety education for consumers and retail establishments. The rule had a 90-day comment period, which ended December 21, 2004. To discuss the proposed rule and solicit comments from interested stakeholders, FDA held three public meetings: October 28, 2004, in College Park, MD; November 9, 2004, in Chicago, IL; and November 16, 2004, in Los Angeles, CA. The comment period was reopened until July 25, 2005, to solicit further comment and information on industry practices and programs that prevent SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into laying hen houses.

Timetable:

Action	Date	FR Cite
NPRM	09/22/04	69 FR 56824
NPRM Comment Period End	12/21/04	
NPRM Reopened Comment Period End	06/09/05	70 FR 24490
NPRM Extension of Reopened Comment Period End	07/25/05	70 FR 33404
Final Action	06/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: John F. Sheehan, Director, Department of Health and Human Services, Food and Drug Administration, Division of Plant and Dairy Food Safety (HFS–315), Room 3B–012, 5100 Paint Branch Parkway, College Park, MD 20740
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RIN: 0910–AC14

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

Legal Authority: 21 USC 355b

Abstract: To require certain 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	
Interim Final Rule	01/03/08	73 FR 402
Final Action	12/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Bldg. 51, Room 6306, Silver Spring, MD 20993–0002
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RIN: 0910–AC35

138. 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	08/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drugs Evaluation and Research, 10903 New Hampshire Avenue, Bldg. 51, Room 6304, Silver Spring, MD 20993–0002
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RIN: 0910–AC55

139. 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

HHS—FDA **Final Rule Stage**

140. 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	10/00/08	

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, 10903 New Hampshire Avenue, Bldg. 51, Room 6316, Silver Spring, MD 20993–0002
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RIN: 0910–AF13

141. EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE

Legal Authority: 21 USC 355; 21 USC 360bbb; 21 USC 371; 42 USC 262

Abstract: The Food and Drug Administration proposed in the Federal Register of December 14, 2006 (75 FR 75147), to amend the regulations governing investigational new drugs (IND) to describe the ways patients may obtain investigational drugs for treatment use under expanded access programs. Such use of investigational drugs would be available to: (1) Individual patients, including in emergencies; (2) intermediate size patient populations; and (3) larger populations under a treatment protocol or treatment IND.

Timetable:

Action	Date	FR Cite
NPRM	12/14/06	71 FR 75147
NPRM Comment Period End	03/14/07	
Final Action	10/00/08	

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, 10903 New Hampshire Avenue, Bldg. 51, Room 6316, Silver Spring, MD 20993–0002
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RIN: 0910–AF14

142. 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 single ingredient bronchodilator products.

Timetable:

Action	Date	FR Cite
NPRM (Amendment – Ephedrine Single Ingredient)	07/13/05	70 FR 40237
Final Action (Technical Amendment)	11/30/07	72 FR 63679
Final Action (Amendment – Ephedrine Single Ingredient)	01/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF32

143. 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 bronchodilators and expectorants.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	07/13/05	70 FR 40232
Final Action (Technical Amendment)	03/19/07	72 FR 12730
Final Action	03/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF33

144. 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)	04/00/09	
NPRM (Amendment) (Pediatric)	To Be	Determined
NPRM (Amendment) (Combinations with Sodium Bicarbonate)	04/00/09	
NPRM (Amendment) (Miscellaneous Issues)	05/00/09	
Final Action (Required Warnings and Other Labeling)	03/00/09	
Final Action (Internal Analgesics)	03/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF36

145. 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	03/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF37

146. 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

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 Rule	04/25/08	73 FR 22720
Final Rule–Correction	06/00/08	
Final Rule Effective	04/27/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Burt Pritchett, Biologist, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, HFV–222, 7519 Standish Place, MPN–4, Rockville, MD 20855
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RIN: 0910–AF46

147. 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	04/00/09	

Regulatory Flexibility Analysis Required: Yes

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HHS—FDA **Final Rule Stage**

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RIN: 0910–AF51

148. 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)	04/00/09	
Final Action (Overindulgence Labeling)	04/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. 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–AF52

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

Long-Term Actions

149. 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, 10903 New Hampshire Avenue, Bldg. 51, Room 6304, Silver Spring, MD 20993–0002
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RIN: 0910–AC23

150. 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 antihistamine labeling claims for the common cold.

Timetable:

Action	Date	FR Cite
Final Action (Amendment) (Common Cold)	05/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF31

151. 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 phenylpropanolamine.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Sinusitis Claim)	08/02/04	69 FR 46119
NPRM (Phenylephrine Bitartrate)	11/02/04	69 FR 63482

Action	Date	FR Cite
NPRM (Phenylpropanolamine)	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 (Phenylpropanolamine)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF34

152. 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. The final action addresses the 2003 proposed rule on patches, plasters, and poultices. The proposed rule will address issues not addressed in previous rulemakings.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	05/00/09	
Final Action (GRASE dosage forms)	05/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF35

153. 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 professional labeling requirements for laxative drug products.

Timetable:

Action	Date	FR Cite
Final Action (Granular Psyllium)	03/29/07	72 FR 14669
Final Action (Laxative Drug Products)	To Be	Determined
NPRM (Professional Labeling)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. 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–AF38

154. 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)	02/19/03	68 FR 7917
NPRM (Amendment) (Emergency First Aid Eyelashes)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. 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

155. 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
ANPRM Comment Period End	08/27/03	
NPRM (Plaque Gingivitis)	To Be	Determined
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF40

156. 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 skin protectant products used to treat fever blisters and cold sores. The second action identifies safe and effective skin protectant active ingredients to treat and prevent diaper rash. The third action addresses astringent active ingredients.

Timetable:

Action	Date	FR Cite
Final Action (Technical Amendments)	02/01/08	73 FR 6014
Final Action (Fever Blisters/Cold Sores)	To Be	Determined
Final Action (Diaper Rash)	05/00/09	
Final Action (Aluminum Acetate) (Technical Amendment)	05/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF42

157. 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. The first document addresses combination products containing sunscreen and insect repellent ingredients. The second document addresses active ingredients reviewed under Time and Extent Applications. The third document is the final action that addresses sunscreen formulation, labeling, and testing requirements for both ultraviolet B and ultraviolet A radiation protection.

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 Comment Period End	11/26/07	
NPRM (Time and Extent)	05/00/09	
Final Action (UVA/UVB)	05/00/09	
NPRM (Sunscreen and Insect Repellent)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. 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–AF43

158. 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. The proposed rule addresses vaginal contraceptive drug products.

Timetable:

Action	Date	FR Cite
Final Action (Warnings)	12/19/07	72 FR 71769
NPRM (Vaginal Contraceptive Drug Products)	05/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF44

159. 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 (Phenylpropanolamine)	12/22/05	70 FR 75988
NPRM (Benzocaine)	05/00/09	
Final Action (Phenylpropanolamine)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF45

160. 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	05/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF53

161. 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	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. 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–AF63

162. 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)	05/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. 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–AF68

163. 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)	05/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. 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–AF70

164. ● FOOD LABELING: SAFE HANDLING STATEMENTS, LABELING OF SHELL EGGS; REFRIGERATION OF SHELL EGGS HELD FOR RETAIL DISTRIBUTION (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; 42 USC 243; 42 USC 264; 42 USC 271

Abstract: Section 101.17 (h) (21 CFR 101.17(h)) describes requirements for the labeling of the cartons of shell eggs that have not been treated to destroy Salmonella microorganisms. Section 115. 50 (21 CFR 115.50) describes requirements for refrigeration of shell eggs held for retail distribution. Section 16.5(a)(4) provides that part 16 does not apply to a hearing on an order for relabeling, diversion, or destruction if shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and sections 101.17(h) and 115.50. FDA amended 21 CFR 101.17(h) on August 20, 2007 (72 FR 46375) to permit the safe handling statement to appear on the inside lid of egg cartons to provide the industry greater flexibility in the placement of the statement. FDA is undertaking a review of 21 CFR sections 101.17(h), 115.50, and 16.5(a)(4) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in sections 101.17(h), 115.50 and 16.5(a)(4) 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 rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

Timetable:

Action	Date	FR Cite
Begin Review	12/00/09	
End Review	12/00/10	

Regulatory Flexibility Analysis Required: Undetermined

Agency Contact: Geraldine A. June, Supervisor, Product Evaluation and Labeling Team, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Brach Parkway, ONLDS (HFS–820), College Park, MD 20740
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RIN: 0910–AG06

165. ● PROCESS CONTROLS FOR ANIMAL FEED INGREDIENTS AND MIXED ANIMAL FEED

Legal Authority: 21 USC 342; 21 USC 371; PL 110–85, sec 1002(a)(2)

Abstract: The Food and Drug Administration (FDA) is proposing regulations for process controls for animal feed ingredients and mixed animal feed to provide greater assurance that marketed animal feed ingredients and mixed feeds intended for all animals, including pets, are safe. This action is being taken as part of the FDA's Animal Feed Safety System initiative. The proposed process controls will apply to animal feed ingredients and mixed animal feed including pet food. This action is also being taken to carry out the requirements of the Food and Drug Administration Amendments Act of 2007. Section 1002(a) directs FDA to establish by regulation processing standards for pet food. This same provision of the law also directs that, in developing these new regulations, FDA obtain input from its stakeholders, including the Association of American Feed Control Officials, veterinary medical associations, animal health organizations, and pet food manufacturers.

Timetable:

Action	Date	FR Cite
NPRM	05/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Kim Young, Deputy Director, Division of Compliance, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, MPN4, Room 106, HFV–230, 7519 Standish Place, Rockville, MD 20855
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RIN: 0910–AG10

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

Completed Actions

166. 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 published 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.

Completed:

Reason	Date	FR Cite
Withdrawn	03/03/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Julie Moss
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RIN: 0910–AF09

167. STATUS OF CERTAIN ADDITIONAL OVER–THE–COUNTER DRUG CATEGORY II AND III ACTIVE INGREDIENTS (COMPLETION OF A 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 initiated a review under section 610 of the Regulatory Flexibility Act for the regulation in section 310.545. The purpose of this review was 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 considered, and solicited 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 was 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 a FDA determination that there is a continual need for this regulation in 310.545, because this section lists ingredients that have not been shown to be safe and effective in OTC drug products for various uses. FDA uses this section in evaluating possible regulatory action.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	12/01/06	
End Review	12/31/07	

Regulatory Flexibility Analysis Required: No

Agency Contact: Walter J. 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

168. MEDICAL DEVICES: CLASSIFICATION/ RECLASSIFICATION; RESTRICTED DEVICES; ANALYTE SPECIFIC REAGENTS (COMPLETION OF A SECTION 610 REVIEW)

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

Abstract: FDA has undertaking a review of 21 CFR sections 809.10 and 809.30 under section 610 of the Regulatory Flexibility Act. The purpose of the review was to determine whether the regulations in sections 809.10 and 809.30 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 numbers of small entities. FDA has solicited comments on, the following (1) The continued need for the regulation in part 809; (2) the nature of complaints or comments received concerning the regulation in sections 809.10 and 809.30; (3) the complexity of the regulation in sections 809.10 and 809.30; (4) the extent to which the regulation in sections 809.10 and 809.30 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 in the area affected by the regulation in sections 809.10 and 809.30.

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 agency did not receive any comments during the review process of sections 809.10 and 809.30 under section 610 review. FDA's review of these regulations concluded that they should be continued without change.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	04/01/07	
End Review	11/30/07	

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), 1350 Piccard Drive, PI50 RM150F, Rockville, MD 20850
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RIN: 0910–AF76

169. NATURAL RUBBER–CONTAINING MEDICAL DEVICE; USER LABELING (COMPLETION OF A 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 has under taken a review of 21 CFR part 801 under section 610 of the Regulatory Flexibility Act. The purpose of the review was to determine whether the regulations in part 801 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 has

solicited comments on the following (1) The continued need for the regulation in part 801; (2) the nature of complaints or comments received concerning the regulation in part 801; (3) the complexity of the regulation in part 801; (4) the extent to which the regulation in part 801 overlap, duplicates, 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 801.

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 agency did not receive any comments during the review process of part 801 under section 610 review. FDA's review of this regulation concluded that it should be continued without change.

Timetable:

Action	Date	FR Cite
Final Action	09/30/97	62 FR 51021
Begin Review of Current Regulation	01/02/07	
End Review of Current Regulation	12/28/07	

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), 1350 Piccard Drive, PI50 RM150F, Rockville, MD 20850
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RIN: 0910–AF77

170. FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS (COMPLETION OF A 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 has reviewed 21 CFR part 54, under section 610 of the Regulatory Flexibility Act. FDA received no comments during the review period mandated by section 610 of the Regulatory Flexibility Act. The purpose of this review was 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 considered and solicited 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 for those affected by the regulations in part 54.

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. FDA did not receive any comments during the review period mandated by section 610 of the Regulatory Flexibility Act. Therefore, no changes will be made to 21 CFR part 54.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	12/01/06	
End Review	12/31/07	

Regulatory Flexibility Analysis Required: No

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RIN: 0910–AF79

171. BEVERAGES: BOTTLED WATER (COMPLETION OF A 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 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. FDA

received two comments on these issues and is considering them.

Timetable:

Action	Date	FR Cite
Begin Review	03/01/07	
End Review	12/31/07	

Regulatory Flexibility Analysis Required: No

Agency Contact: Geraldine A. June, Supervisor, Product Evaluation and Labeling Team, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Brach Parkway, ONLDS (HFS–820), College Park, MD 20740
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RIN: 0910–AF80

172. 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 (COMPLETION OF A 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 undertook a review of sections 101.54 and 101.60 under section 610 of the Regulatory Flexibility Act. The purpose of this review was 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 solicited 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. No comments were received. FDA's review of these regulations concluded that they should be continued without change.

Timetable:

Action	Date	FR Cite
Begin Review	12/01/06	
End Review	11/30/07	

Regulatory Flexibility Analysis Required: No

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RIN: 0910–AF83

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

Proposed Rule Stage

173. 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	09/00/08	

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

174. REVISIONS TO HIPAA CODE SETS (CMS–0013–P) (SECTION 610 REVIEW)

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	06/00/08	

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

175. HOME AND COMMUNITY–BASED SERVICES (HCBS) STATE PLAN OPTION (CMS–2249–F) (SECTION 610 REVIEW)

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

Abstract: This rule amends the Medicaid regulations to define and describe the home and community-based State plan services implementing the 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	04/04/08	73 FR 18676
NPRM Comment Period End	06/03/08	
Final Action	09/00/08	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AO53

176. 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	05/00/08	

Regulatory Flexibility Analysis Required: Yes

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

177. 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.

Timetable:

Action	Date	FR Cite
NPRM	05/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Michele Hudson, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AP15

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

Legal Authority: BBA; PPRA; BIPA; MMA; 42 USC 1302 et al

Abstract: This rule would revise the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from continuing experience with this system and to implement certain related provisions of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. In addition, the proposed rule describes proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. The rule also proposes changes to the Ambulatory Surgical Center Payment System list of services and rates. These changes would be applicable to services furnished on or after January 1 annually.

Timetable:

Action	Date	FR Cite
NPRM	07/00/08	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP17

179. ● REQUIREMENTS FOR LONG TERM CARE FACILITIES: HOSPICE SERVICES (CMS–3140–P) (SECTION 610 REVIEW)

Legal Authority: 42 USC 1302; 42 USC 1395hh

Abstract: This proposed rule would establish requirements that long-term care (LTC) facilities must have an agreement with hospice agencies when hospice care is provided in a long-term care facility to participate in the Medicare and Medicaid programs. We are proposing these new requirements to ensure that quality hospice care is provided to eligible residents.

Timetable:

Action	Date	FR Cite
NPRM	08/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Adriene Brooks, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare &

HHS—CMS **Proposed Rule Stage**

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RIN: 0938–AP32

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

180. MEDICARE AND MEDICAID PROGRAMS; HOSPICE CARE CONDITIONS OF PARTICIPATION (CMS–3844–F) (SECTION 610 REVIEW)

Legal Authority: 42 USC 1302; 42 USC 1395hh

Abstract: This final rule is a regulatory reform initiative that revises existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The requirements focus on the actual care delivered to patients and patients' families by hospices and the results of that care, reflect an interdisciplinary view of patient care, and allow hospices greater flexibility in meeting quality standards. 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	05/27/05	70 FR 30840
Final Action	05/00/08	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AH27

181. INPATIENT PSYCHIATRIC FACILITY PROSPECTIVE PAYMENT SYSTEM—UPDATE FOR RATE YEAR BEGINNING JULY 1, 2008 (RY 2009) (CMS–1401–N)

Legal Authority: PL 106–113, sec 124 BBRA

Abstract: This notice updates the Inpatient Psychiatric Facility Prospective Payment System for rate year (RY) 2009.

Timetable:

Action	Date	FR Cite
Notice	05/00/08	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AO92

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

Legal Authority: sec 123 PL 106–113; sec 307(b) PL 106–554; sec 114 of PL 110–173

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

Timetable:

Action	Date	FR Cite
NPRM	01/29/08	73 FR 5342
NPRM Comment Period End	03/24/08	
Final Action	05/00/08	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AO94

183. ● CHANGES TO LONG TERM CARE PROSPECTIVE PAYMENT SYSTEM BASED ON SPECIFIC PROVISIONS IN THE MEDICARE, MEDICAID, AND SCHIP EXTENSION ACT OF 2007 (CMS–1493–IFC)

Legal Authority: Provisions of sec 114 of PL 110–173 (MMSE Act of 2007); sec 1886 (d) of the Social Security Act as amended by the sec 114 of PL 110–173 (MMSE Act of 2007)

Abstract: This rule implements provisions of the Medicare, Medicaid, and SCHIP Extension Act of 2007 relating to long term care hospitals. In addition to amending section 1861 of the Act with a new definition of LTCHs, this rule includes provisions that are effective on the date of enactment (12/29/07). Specifically, the statute imposes a 3-year delay in implementation of certain payment policies that set percentage thresholds for LTCH patients admitted from certain referring hospitals and raises the percentage threshold for those LTCHs unaffected by the 3-year delay. The legislation imposes the same 3-year delay on the implementation of a particular payment adjustment for short-stay patients and also for the possible application of a one-time adjustment to the standard Federal rate. The statute also required a change in the Federal rate for RY 2008, (effective 4/1/08). Additionally, the statute created a 3-year moratorium on the establishment of new LTCHs and LTCH satellites and on bed expansion in existing LTCHs, subject to significant exceptions.

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/00/08	

HHS—CMS **Final Rule Stage**

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP33

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

Long-Term Actions

184. SURETY BOND REQUIREMENT FOR SUPPLIERS OF DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) (CMS–6006–F) (SECTION 610 REVIEW)

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

185. ESTABLISHING ADDITIONAL MEDICARE PROVIDER AND SUPPLIER ENROLLMENT SAFEGUARDS (CMS–6045–P) (SECTION 610 REVIEW)

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	12/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP01

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

Completed Actions

186. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS–3818–F) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: 42 USC 1395rr et al

Abstract: This final rule revises the requirements that end stage renal disease (ESRD) facilities must meet to be certified under the Medicare program.

Timetable:

Action	Date	FR Cite
NPRM	02/04/05	70 FR 6184
Notice	02/04/08	73 FR 6451
Final Action	04/15/08	73 FR 20369

Regulatory Flexibility Analysis Required: Yes

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