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Part VI

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, Chs. II, III, and XIII

Unified Agenda of Federal Regulatory and Deregulatory Actions

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual regulations agenda.

SUMMARY: The Department's semiannual Agenda of Regulatory and Deregulatory Actions forecasts the rulemaking activities that we expect to undertake over the foreseeable future. We focus primarily on those areas of work anticipated to result in publication of Notices of Proposed Rulemaking or of Final Rules within the next 12 months. (Please note that the abstracts included below relate only to those prospective rulemakings that are likely to have a significant economic impact on a substantial number of small entities; the Regulatory Flexibility Act of 1980 requires dissemination of this information in the paper edition of the **Federal Register**. The complete HHS Agenda is accessible online at www.reginfo.gov.)

FOR FURTHER INFORMATION CONTACT: by e-mail, John.Gallivan@hhs.gov; by fax, (202) 205-2135; by telephone, (202) 205-9165.

SUPPLEMENTARY INFORMATION:

The Regulatory Flexibility Act of 1980 and Executive Order 12866 require semi-annual publication of an inventory outlining all current and projected rulemakings. The purpose of this exercise is to inform the public about regulatory actions under development across the Department, and to provide an opportunity for all concerned with the impact of these actions to participate in their development at an early stage.

The regulatory actions capsulized in this Agenda do not necessarily reflect the policy perspectives of the Obama Administration. The statutorily dictated timing of the Agenda caused the Department to initiate preparation of the requisite information before the Department's policy officials had the opportunity to conduct a full review. This Agenda thus reflects ongoing efforts by HHS to comply with existing statutory obligations, or to effect improvements at the program-implementation level based on experience in administering existing programs. By contrast, the timing of the October 2009 Agenda will, obviously, provide the Department with an opportunity to set out a regulatory agenda that does reflect current policy directions of the Obama Administration.

Public commentary is invited. Comments may be directed to the agency officials cited at the conclusion of each entry. If early attention at the Secretary's level appears needed, comments should be sent to: Ashley Files Flory, Acting Executive Secretary to the Department, Suite 603H, 200 Independence Avenue SW., Washington, DC 20201.

Dated: April 3, 2009.

Ashley Files Flory,

Acting Executive Secretary to the Department.

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
147	Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addition **(Section 610 Review)**	0930–AA14

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

Sequence Number	Title	Regulation Identifier Number
148	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—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
149	Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Animal Importation Regulations	0920–AA14
150	Control of Communicable Diseases: Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Nonhuman Primate Regulations	0920–AA23

HHS

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
151	Control of Communicable Diseases Foreign Quarantine	0920–AA12
152	Control of Communicable Diseases: Interstate Quarantine, Passenger Information	0920–AA27

Centers for Disease Control and Prevention—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
153	Possession, Use and Transfer of Select Agents and Toxins **(Section 610 Review)**	0920–AA32

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
154	Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution **(Section 610 Review)**	0910–AG06
155	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures **(Section 610 Review)**	0910–AG14

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
156	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics	0910–AC52
157	Over-The-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
158	Over-The-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
159	Over-The-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
160	Over-The-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
161	Pediatric Dosing for Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-The-Counter Human Use; Proposed Amendment of Final Monograph	0910–AG12

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
162	Prevention of Salmonella Enteritidis in Shell Eggs	0910–AC14
163	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
164	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
165	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910–AF11
166	Over-The-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
167	Over-The-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
168	Over-The-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
169	Over-The-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
170	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
171	Substances Prohibited From Use in Animal Food or Feed To Prevent the Transmission of Bovine Spongiform Encephalopathy	0910–AF46
172	Use of Materials Derived From Cattle in Human Food and Cosmetics	0910–AF47
173	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61
174	Over-The-Counter (OTC) Drug Review—Acne Drug Products Containing Benzoyl Peroxide	0910–AG00

HHS

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
175	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
176	Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements	0910–AB88
177	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
178	Over-The-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
179	Over-The-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
180	Over-The-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40
181	Over-The-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44
182	Over-The-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products	0910–AF51
183	Over-The-Counter (OTC) Drug Review—Antacid Products	0910–AF52
184	Over-The-Counter (OTC) Drug Review—Skin Bleaching Products	0910–AF53
185	Over-the-Counter (OTC) Drug Review—Stimulant Drug Products	0910–AF56
186	Over-The-Counter Antidiarrheal Drug Products	0910–AF63
187	Over-The-Counter (OTC) Drug Review—Poison Treatment Drug Products	0910–AF68
188	Over-The-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
189	Over-The-Counter (OTC) Drug Review—Urinary Analgesic Drug Products	0910–AF70
190	Status of Certain Additional Over-the-Counter Drug Category II Active Ingredients	0910–AF95
191	Process Controls for Animal Feed Ingredients and Mixed Animal Feed	0910–AG10

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
192	Requirements for Submission of In Vivo Bioequivalence Data	0910–AC23
193	Cochineal Extract and Carmine Label Declaration	0910–AF12
194	Obstetrical and Gynecological Devices; Designation of Special Controls for Male Condoms Made of Natural Rubber Latex	0910–AF21
195	Food Labeling; Serving Sizes and Nutrition Labeling **(Completion of a Section 610 Review)**	0910–AF99

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
196	Changes to the Hospital Inpatient and Long-Term Care Prospective Payment System for FY 2010 (CMS-1406-P)	0938–AP39
197	Revisions to Payment Policies Under the Physician Fee Schedule For CY 2010 (CMS-1413-P)	0938–AP40
198	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2010 (CMS-1414-P)	0938–AP41
199	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2010 (CMS-1410-P)	0938–AP46

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
200	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P) **(Section 610 Review)**	0938–AG81
201	Electronic Claims Attachments Standards (CMS-0050-IFC)	0938–AK62
202	Home and Community-Based Services (HCBS) State Plan Option (CMS-2249-F) **(Section 610 Review)**	0938–AO53
203	Medicaid Graduate Medical Education (CMS-2279-F)	0938–AO95
204	Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P) **(Section 610 Review)**	0938–AP32

HHS

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
205	Updates to Electronic Transactions (Version 5010) (CMS-0009-F) **(Completion of a Section 610 Review)**	0938–AM50
206	Revisions to HIPAA Code Sets (CMS-0013-F) **(Completion of a Section 610 Review)**	0938–AN25
207	Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-6006-F) **(Completion of a Section 610 Review)**	0938–AO84
208	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2009 (CMS-1404-F)	0938–AP17
209	Revisions to Payment Policies Under the Physician Fee Schedule for CY 2009 (CMS-1403-FC)	0938–AP18
210	Home Health Prospective Payment System Refinements and Rate Update for CY 2009 (CMS-1555-N)	0938–AP20
211	Changes to Long-Term Care Prospective Payment System Based on Specific Provisions in the Medicare, Medicaid, and SCHIP Extension Act of 2007 (CMS-1493-F)	0938–AP33

Department of Health and Human Services (HHS) — Proposed Rule Stage
Substance Abuse and Mental Health Services Administration (SAMHSA)

147. OPIOID DRUGS IN MAINTENANCE OR DETOXIFICATION TREATMENT OF OPIATE ADDITION (SECTION 610 REVIEW)

Legal Authority: 21 USC 823 (9); 42 USC 257a; 42 USC 290aa(d); 42 USC 290dd–2; 42 USC 300xx–23; 42 USC 300x–27(a); 42 USC 300y–11

Abstract: This proposed rule, when finalized will modify the regulatory dispensing restrictions under 42 CFR part 8 for the drug substance buprenorphine. This medication is used to treat kersin and other opioid addiction.

Timetable:

Action	Date	FR Cite
NPRM	09/00/09	

Regulatory Flexibility Analysis Required: No

Agency Contact: Nicholas Reuter, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, One Choke Cherry Rd, Suite 2–1063, Rockville, MD 20857
Phone: 240 276–2716

RIN: 0930–AA14

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

148. 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) — Proposed Rule Stage
Centers for Disease Control and Prevention (CDC)

149. FOREIGN QUARANTINE REGULATIONS, PROPOSED REVISION OF HHS/CDC ANIMAL IMPORTATION REGULATIONS

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. The Secretary has designated the authority to prevent the introduction of diseases from foreign

HHS—CDC **Proposed Rule Stage**

countries to the Director, Centers for Disease Control and Prevention (CDC). CDC also enforces entry requirements for certain animals, etiologic agents and vectors deemed to be of public health significance. Currently the regulations restrict the importation of nonhuman primates, dogs, cats, small turtles, etiologic agents, hosts and vectors, such as bats (42 CFR sections 71.53, 71.51, 71.52, 71.54). In addition, CDC has recently issued a series of emergency orders, restricting the importation of African rodents (42 CFR section 71.56) and civets (67 FR 3364-01). CDC is issuing this Notice of Proposed Rulemaking (NPRM) to revise the regulations for importation of certain animals and vectors into the Unite States (42 CFR parts 71, Subpart F).

Timetable:

Action	Date	FR Cite
ANPRM	07/31/07	72 FR 41676
Notice Extending ANPRM Comment Period	10/01/07	72 FR 55729
NPRM	12/00/09	

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: 404 498–1600

RIN: 0920–AA14

150. CONTROL OF COMMUNICABLE DISEASES: FOREIGN QUARANTINE REGULATIONS, PROPOSED REVISION OF HHS/CDC NONHUMAN PRIMATE REGULATIONS

Legal Authority: 42 U.S.C. 264

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. The Secretary has delegated the authority to prevent the introduction of diseases from foreign countries to the Director, CDC. CDC also enforces entry requirements for certain animals, etiologic agents, and vectors deemed to be of public health significance. CDC is proposing to amend its regulations related to the importation of live nonhuman primates (NHPs) by extending existing requirements for the importation of cynomolgus, African green, and rhesus monkeys to all NHPs. The agency also is proposing to reduce the frequency at which importers of the three species are required to renew their registrations, (from every 180 days to every two years). CDC proposes to incorporate existing guidelines into the regulations and add new provisions to address NHPs imported as part of a circus or trained animal act, NHPs imported by zoological societies, the transfer of NHPs from approved laboratories, and non-live imported NHP products. CDC is also proposing that all NHPs be imported only through ports of entry where a CDC quarantine station is located.

Timetable:

Action	Date	FR Cite
NPRM	12/00/09	

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: 404 498–1600

RIN: 0920–AA23

Department of Health and Human Services (HHS) — Final Rule Stage
Centers for Disease Control and Prevention (CDC)

151. CONTROL OF COMMUNICABLE DISEASES FOREIGN QUARANTINE

Legal Authority: 42 USC 243; 42 USC 248 and 249

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. This rule (42 CFR part 71) will update and improve CDC's response to both global and domestic disease threats by creating a multi-tiered illness detection and response process thus substantially enhancing the public health system's ability to slow the introduction, transmission, and spread of communicable disease. The rule will also modify current Federal regulations governing the apprehension, quarantine isolation and conditional release of individuals suspected of carrying a quarantinable disease while respecting individual autonomy. 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	09/00/09	

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: 404 498–1600

RIN: 0920–AA12

152. CONTROL OF COMMUNICABLE DISEASES: INTERSTATE QUARANTINE, PASSENGER INFORMATION

Legal Authority: 25 USC 198.231; 25 USC 1661; 42 USC 243; 42 USC 248; 42 USC 249; 42 USC 264; 42 USC 266 to 268; 42 USC 270 to 272; 42 USC 2001

HHS—CDC **Final Rule Stage**

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases 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 CDC Director has been delegated the responsibility for carrying out these regulations. The Director's authority to investigate suspected cases and potential spread of communicable disease among interstate travelers is thus not limited to those known or suspected of having a quarantinable disease, but rather all communicable diseases that may necessitate a public health response.

Among the fundamental components of the public health response to the report of a person with a communicable disease is the identification and evaluation of individuals who may have been exposed. This provision, which was proposed section 70.4, would require any airline operating in interstate traffic to solicit and electronically submit certain passenger information to CDC for use in contact tracing when necessary to protect the vital interests of an individual, or other persons, in regard to significant health risks.

Timetable:

Action	Date	FR Cite
NPRM	11/30/05	70 FR 71892
Final Action	12/00/09	

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: 404 498–1600

RIN: 0920–AA27

Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)

Long-Term Actions

153. ● POSSESSION, USE AND TRANSFER OF SELECT AGENTS AND TOXINS (SECTION 610 REVIEW)

Legal Authority: PL 107–188

Abstract: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the HHS Secretary to regulate the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. These regulations are set forth at 42 CFR 73. Criteria used to determine whether a select agent or toxin should be included under the provisions of these regulations are based on: 1) the effect on human health as a reuslt of exposure to the agent or toxin, 2) the degree of contagiousness of the agent or toxin, 3) the methods by which the agent or toxin is transferred to humans, 4) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent andy illness resulting from infection by the agent or toxin, and 5) any other criteria, including the needs of children and other vulnerable populations that the HHS Secretary considers appropriate. Based on these criteria, we are proposing to amend the list of HHS select agents and toxins by adding Chapare virus to the list. After consulting with subject matter experts from CDC, the National Institutes of Health (NIH), the Food Drug Administration (FDA), the United States Department of Agriculture (USDA) /Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/CVB (Center for Veterinary Biologics), and the Department of Defense (DOD)/United States Army Medical Research Institute for Infectious Diseases (USAMRIID) and review of relevant published studies, we believe the Chapare virus should be added to the list of HHS select agents and toxins based on our conclusion that the Chapare virus has been phylogenetically identified as a Clade B arenavirus and is closely related to other South American arenaviruses that cause haemorrhagic fever, particularly Sabia virus.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: No

Agency Contact: Robbin Weyant, Department of Health and Human Services, Centers for Disease Control and Prevention, CLFT Building 20, Room 4202, 1600 Clifton Road NE., Atlanta, GA 30333
Phone: 404 718–2000

RIN: 0920–AA32

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

Prerule Stage

154. 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 to 1455; 21 USC 321; 21 USC 331; 21 USC 342 and 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, (HFS–820), 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1802
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Email: geraldine.june@fda.hhs.gov

RIN: 0910–AG06

155. PRESCRIPTION DRUG MARKETING ACT OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992; POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES (SECTION 610 REVIEW)

Legal Authority: 21 USC 331; 21 USC 333; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 381

Abstract: FDA is undertaking a review of 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) 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 in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (2) the nature of complaints or comments received from the public concerning the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (3) the complexity of the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (4) the extent to which the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State and local governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763).

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	11/24/08	
End Review of Current Regulation	12/00/09	

Regulatory Flexibility Analysis Required: Yes

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, 10903 New Hampshire Avenue, Bldg. 51, Room 6234, Silver Spring, MD 20993–0002
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RIN: 0910–AG14

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

Proposed Rule Stage

156. 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	09/00/09	

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
Phone: 301 796–3471
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Email: martha.nguyen@fda.hhs.gov

RIN: 0910–AC52

157. 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 to 360a; 21 USC 371 to 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
Reopening of Administrative Record	08/25/00	65 FR 51780
NPRM (Amendment) (Common Cold)	04/00/10	

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
Phone: 301 796–0885
Fax: 301 796–9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910–AF31

158. 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 to 360a; 21 USC 371 to 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 final action will address laxative drug products. The first NPRM listed will address the professional labeling for sodium phosphate drug products. The second NPRM listed will address all other 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—Sodium Phosphate)	09/00/09	
NPRM (Professional Labeling)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF38

159. 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 to 360a; 21 USC 371 to 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 active ingredients reviewed under Time and Extent Applications. The second action is the final action that addresses sunscreen formulation, labeling, and testing requirements for both ultraviolet B and ultraviolet A radiation protection. The third 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 Comment Period End	12/26/07	
NPRM (Time and Extent)	09/00/09	
Final Action (UVA/UVB)	09/00/09	
NPRM (Sunscreen and Insect Repellent)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF43

160. 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 actions address the ingredient benzocaine.

Timetable:

Action	Date	FR Cite
NPRM (Phenylpropanolamine)	12/22/05	70 FR 75988
NPRM (Benzocaine)	09/00/09	
Final Action (Phenylpropanolamine)	05/00/10	
Final Action (Benzocaine)	To Be	Determined

HHS—FDA **Proposed Rule Stage**

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF45

161. PEDIATRIC DOSING FOR COUGH, COLD, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE; PROPOSED AMENDMENT OF FINAL MONOGRAPH

Legal Authority: 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360(a); 21 USC 371 to 371(a)

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a monograph 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 propose changes to the final monograph to address safety and efficacy issues associated with pediatric cough and cold products.

Timetable:

Action	Date	FR Cite
NPRM	09/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG12

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

Final Rule Stage

162. 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 was 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. 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

Action	Date	FR Cite
NPRM Extension of Reopened Comment Period End	07/25/05	70 FR 33404
Final Action	07/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AC14

163. MEDICAL GAS CONTAINERS AND CLOSURES; CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS

Legal Authority: 21 USC 321; 21 USC 351 to 21 USC 353

Abstract: The Food and Drug Administration is amending its current good manufacturing practice regulations and other regulations to clarify and strengthen requirements for the label, color, dedication, and design of medical gas containers and closures. Despite existing regulatory requirements and industry standards for medical gases, there have been repeated incidents in which cryogenic containers of harmful industrial gases have been connected to medical oxygen supply systems in hospitals and nursing homes, and subsequently administered to patients. These incidents have resulted in death and serious injury. There have also been several incidents involving high-pressure medical gas cylinders that have resulted in death and injuries to patients. These amendments, together with existing regulations, are intended to ensure that the types of incidents that have occurred in the past, as well as other types of foreseeable and potentially deadly medical gas mixups, do not occur in the future.

Timetable:

Action	Date	FR Cite
NPRM	04/10/06	71 FR 18039
NPRM Comment Period End	07/10/06	
Final Action	09/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AC53

164. 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 final 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	08/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AC55

165. 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 parts 201.56, 201.57, and 201.80).

Timetable:

Action	Date	FR Cite
NPRM	05/29/08	73 FR 30831
NPRM Comment Period End	08/27/08	
Final Action	03/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF11

166. 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 to 360a; 21 USC 371 to 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)	09/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF32

167. 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 to 360a; 21 USC 371 to 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	09/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF33

168. 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
Final Action (GRASE dosage forms)	12/00/09	
NPRM (Amendment)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF35

169. 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)	05/00/10	
NPRM (Amendment) (Pediatric)	To Be	Determined
NPRM (Amendment) (Combinations With Sodium Bicarbonate)	05/00/10	
NPRM (Amendment) (Miscellaneous Issues)	05/00/10	
Final Action (Required Warnings and Other Labeling)	05/00/09	
Final Action (Internal Analgesics)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF36

170. 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 addresses astringent active ingredients. The third action identifies safe and effective skin protectant active ingredients to treat and prevent diaper rash.

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 (Aluminum Acetate) (Technical Amendment)	03/06/09	74 FR 9759
Final Action (Diaper Rash)	12/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF42

171. 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. FDA is correcting the final rule on BSE that appeared in the Federal Register of April 25, 2008 (73 FR 22719-22758). The final rule inadvertently published with incorrect dollar amounts in two separate areas: the summary of economic impacts and the paperwork burden table.

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	10/23/08	73 FR 63072
Final Rule Effective	04/27/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF46

172. USE OF MATERIALS DERIVED FROM CATTLE IN HUMAN FOOD AND COSMETICS

Legal Authority: 21 USC 342; 21 USC 361; 21 USC 371

Abstract: On July 14, 2004, FDA issued an interim final rule (IFR), effective immediately, to prohibit the use of certain cattle material and to address the potential risk of bovine spongiform encephalopathy (BSE) in human food, including dietary supplements, and cosmetics. Prohibited cattle materials under the IFR include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) beef. Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. This action minimizes human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE.

On September 7, 2005, FDA amended the IFR to permit the use of small intestine in human food and cosmetics if it is effectively removed from the distal ileum. The amendment also clarified that milk and milk products, hides, and tallow derivatives are not prohibited for use in human food and cosmetics.

On April 17, 2008, FDA amended the IFR so that FDA may designate a country as not subject to certain BSE-related restrictions relating to prohibited cattle materials applicable to human food and cosmetics.

Comments submitted in response to the July 14, 2004 IFR that were not addressed in the September 7, 2005 and April 17, 2008 amendments will be addressed in the final rule. The final rule also will respond to comments submitted following the September 7, 2005 and April 17, 2008 amendments.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/14/04	69 FR 42256
Interim Final Rule Effective	07/14/04	
Interim Final Rule Comment Period End	10/12/04	
Interim Final Rule (Amendments)	09/07/05	70 FR 53063
Interim Final Rule (Amendments) Effective	10/07/05	
Interim Final Rule (Amendments) Comment Period End	11/07/05	
Interim Final Rule (Amendments)	04/17/08	73 FR 20785
Interim Final Rule (Amendments) Comment Period End	07/16/08	
Interim Final Rule (Amendments) Effective	07/16/08	
Final Action	09/00/09	

Regulatory Flexibility Analysis Required: Yes

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HHS—FDA **Final Rule Stage**

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RIN: 0910–AF47

173. 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 and 343; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 264

Abstract: The final rule will require owners or consignees to label imported food that is refused entry into the United States. The label will read, ''UNITED STATES: REFUSED ENTRY.'' The proposal describes 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	09/18/08	73 FR 54106
NPRM Comment Period End	12/02/08	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF61

174. OVER–THE–COUNTER (OTC) DRUG REVIEW—ACNE DRUG PRODUCTS CONTAINING BENZOYL PEROXIDE

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 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 acne drug products containing benzoyl peroxide.

Timetable:

Action	Date	FR Cite
Final Action	10/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG00

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

Long-Term Actions

175. POSTMARKETING SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

Legal Authority: 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262 and 263; 42 USC 263a to 263n; 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	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AA97

176. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS

Legal Authority: 21 USC 321; 21 USC 342 and 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	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AB88

177. 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 to 360a; 21 USC 371 to 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
NPRM (Phenylpropanol amine)	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 (Phenylpropanol amine)	05/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF34

178. 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	05/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF37

179. 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 Eyewashes)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF39

180. 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 to 360a; 21 USC 371 to 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

181. 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 to 360a; 21 USC 360gg to 360ss; 21 USC 371 to 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)	05/00/10	

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–AF44

182. 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	05/00/10	

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–AF51

183. 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)	05/00/10	
Final Action (Overindulgence Labeling)	05/00/10	

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

184. 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 to 360a; 21 USC 371 to 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	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF53

185. 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 to 360a; 21 USC 371 to 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)	05/00/10	

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

186. 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 to 360a; 21 USC 371 to 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. These actions address new labeling for antidiarrheal drug products.

Timetable:

Action	Date	FR Cite
NPRM (Proposed New Labeling)	To Be	Determined
Final Action (New 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–AF63

187. 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)	06/00/10	

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

188. 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 to 360a; 21 USC 371 to 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 final actions listed will address the healthcare, consumer, and first aid antiseptic drug products respectively.

Timetable:

Action	Date	FR Cite
NPRM (Healthcare)	06/17/94	59 FR 31402
NPRM (Food Handlers)	To Be	Determined
NPRM (Testing)	To Be	Determined
NPRM (Consumer)	To Be	Determined
Final Action (Healthcare)	To Be	Determined
Final Action (Consumer)	To Be	Determined

Action	Date	FR Cite
Final Action (First Aid Antiseptic)	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

189. 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 to 360a; 21 USC 371 to 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)	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–AF70

190. STATUS OF CERTAIN ADDITIONAL OVER–THE–COUNTER DRUG CATEGORY II ACTIVE INGREDIENTS

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

Abstract: The Food and Drug Administration (FDA) is proposing that certain ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective or are misbranded. FDA is issuing this proposed rule because we did not receive any data and information on these ingredients in response to our request on December 31, 2003 (68 FR 75585). This proposed rule is part of FDA's ongoing review of OTC drug products.

Timetable:

Action	Date	FR Cite
NPRM	06/19/08	73 FR 34895
NPRM Comment Period End	09/17/08	
Final Action	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–AF95

191. 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	04/00/10	
NPRM Comment Period End	07/00/10	

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

192. REQUIREMENTS FOR SUBMISSION OF IN VIVO BIOEQUIVALENCE DATA

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

Completed:

Reason	Date	FR Cite
Final Action	01/16/09	74 FR 2849

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Jennifer L. Stevens
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RIN: 0910–AC23

193. COCHINEAL EXTRACT AND CARMINE LABEL DECLARATION

Legal Authority: 21 USC 379e(b)

Abstract: The Agency published a final rule on January 5, 2009, 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 final rule was issued in response to adverse event reports received by FDA and to a citizen petition submitted to FDA.

Completed:

Reason	Date	FR Cite
Final Action	01/05/09	74 FR 207
Final Rule—Objection Period End	02/04/09	
Final Rule–Confirmation of Effective Date	03/11/09	74 FR 10483

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF12

194. OBSTETRICAL AND GYNECOLOGICAL DEVICES; DESIGNATION OF SPECIAL CONTROLS FOR MALE CONDOMS MADE OF NATURAL RUBBER LATEX

Legal Authority: 21 USC 360c

Abstract: The classification regulation for condoms would be amended to specify a labeling guidance document as a special control for condoms made from natural rubber latex. The new special control guidance document would identify issues presented by these devices, and would provide detailed recommendations for labeling to address these issues. FDA believes that addressing the issues identified in the guidance, either by following the recommendations in the guidance or by some other means that provide equivalent assurances of safety and effectiveness, together with the general controls, will provide a reasonable assurance of the safety and effectiveness of these devices. These labeling recommendations are also consistent with the labeling requirements of 21 CFR part 801. The rule will demonstrate how the Agency is addressing the congressional directive of Public Law 106-554 that FDA review condom labeling to assure that the information regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases is medically accurate.

Completed:

Reason	Date	FR Cite
Final Action	11/10/08	73 FR 66522

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF21

195. FOOD LABELING; SERVING SIZES AND NUTRITION LABELING (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 331; 21 USC 342 and 343; 21 USC 348; 21 USC 371

Abstract: Section 101.9 (21 CFR 101.9) describes the nutrition labeling requirements for foods. Section 101.12 (21 CFR 101.12) specifies the reference amount customarily consumed per eating occasion for each food category. The reference amount customarily consumed of a food is the basis for the serving size that is declared in the food's nutrition labeling. Under section 101.9, the serving size must be expressed in a common household measure that is appropriate to the food. The most recent change to sections 101.9 and 101.12 was in 1999, when FDA amended these regulations to reduce the reference amount customarily consumed for baking powder, baking soda, and pectin, and to include 1/8 teaspoon as an allowable unit of household measure for nutrition labeling purposes. FDA has completed a review of sections 101.9 and 101.12 under section 610 of the Regulatory Flexibility Act. The purpose of this review was 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 solicited 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. FDA received no comments and concluded that there is a continuing

need for the nutrition labeling and serving size regulations in sections 101.9 and 101.12 and that these regulations should be retained without change.

Timetable:

Action	Date	FR Cite
Begin Review	12/12/08	
End Review	02/10/09	

Regulatory Flexibility Analysis Required: No

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RIN: 0910–AF99

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

Proposed Rule Stage

196. CHANGES TO THE HOSPITAL INPATIENT AND LONG–TERM CARE PROSPECTIVE PAYMENT SYSTEM FOR FY 2010 (CMS–1406–P)

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

Abstract: This major rule proposes to revise the Medicare hospital inpatient and Long Term Care 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	04/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Tiffany Swygert, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Div of Acute Care, Hosp and Ambulatory Policy Group, Mailstop C4–25–11, 7500 Security Blvd, Baltimore, MD 21244
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RIN: 0938–AP39

197. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CY 2010 (CMS–1413–P)

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1871

Abstract: This major proposed rule would revise payment polices under the physician fee schedule, as well as other policy changes to payment under Part B.

Timetable:

Action	Date	FR Cite
NPRM	06/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP40

198. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM FOR CY 2010 (CMS–1414–P)

Legal Authority: BBA; PPRA; BIPA; MMA; MMSEA; MIPPA; DRA; TRHCA

Abstract: This major rule would revise the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our 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	06/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Alberta Dwivedi, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare Management, Mailstop C5–01–26, 7500 Security Blvd, Baltimore, MD 21244
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RIN: 0938–AP41

199. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2010 (CMS–1410–P)

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

Abstract: This major rule proposes updates to the payment rates used under the SNF PPS beginning October 1, 2009.

Timetable:

Action	Date	FR Cite
NPRM	05/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: William Ullman, Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicare Management, Mailstop C5–06–27, 7500 Security Boulvard, Baltimore, MD 21244
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RIN: 0938–AP46

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

Long-Term Actions

200. 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	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined

Agency Contact: Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AG81

201. ELECTRONIC CLAIMS ATTACHMENTS STANDARDS (CMS–0050–IFC)

Legal Authority: 42 USC 1320d–2(a)(2)(B)

Abstract: This rule sets forth electronic standards for health care claims attachments. The standards are required by the Health Insurance Portability and Accountability Act of 1996. They will be used to transmit clinical or administrative data for claims adjudication purposes.

Timetable:

Action	Date	FR Cite
NPRM	09/23/05	70 FR 55989
Interim Final Rule	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AK62

202. 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 major 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	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AO53

203. MEDICAID GRADUATE MEDICAL EDUCATION (CMS–2279–F)

Legal Authority: title 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	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AO95

204. 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	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP32

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

Completed Actions

205. UPDATES TO ELECTRONIC TRANSACTIONS (VERSION 5010) (CMS–0009–F) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: sec 1171 to 1179 of the Social Security Act; Deficit Reduction Act of 2005, PL 109–171, sec 6035

Abstract: This rule adopts new versions of the X12 suite of HIPAA transactions and allows the industry to use the most up-to-date versions of the HIPAA transactions for claims and remittance advice. The rule will also adopt an updated pharmacy transactions standard for retail pharmacy claims.

Timetable:

Action	Date	FR Cite
NPRM	08/22/08	73 FR 49741
NPRM Comment Period End	10/21/08	
Final Action	01/16/09	74 FR 3296

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AM50

206. REVISIONS TO HIPAA CODE SETS (CMS–0013–F) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: PL 104–191

Abstract: This rule revises 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	08/22/08	73 FR 49795
NPRM Comment Period End	10/21/08	
Final Action	01/16/09	74 FR 3328

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AN25

207. SURETY BOND REQUIREMENT FOR SUPPLIERS OF DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) (CMS–6006–F) (COMPLETION OF A 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	01/02/09	74 FR 166

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AO84

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

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

Abstract: This rule revises 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 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 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.

Completed:

Reason	Date	FR Cite
Final Action	11/18/08	73 FR 68501

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP17

209. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CY 2009 (CMS–1403–FC)

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1871

Abstract: This major rule makes changes affecting Medicare Part B payment to physicians and other Part B suppliers.

Completed:

Reason	Date	FR Cite
Final Action	11/19/08	73 FR 69725

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP18

210. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM REFINEMENTS AND RATE UPDATE FOR CY 2009 (CMS–1555–N)

Legal Authority: Social Security Act, secs 1102 and 1871; (42 USC 1302 and 1395(hh)); Social Security Act, sec 1895 (42 USC 1395fff)

Abstract: Section 1895 of the Act requires that the Home Health PPS be adjusted in a prospective manner specified by the Secretary by the home health increase percentage applicable to the year involved.

HHS—CMS

Completed Actions

Completed:

Reason	Date	FR Cite
Notice	11/03/08	73 FR 65351

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP20

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

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 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 (December 29, 2007). 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 April 1, 2008). 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.

Completed:

Reason	Date	FR Cite
Withdrawn	01/29/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP33

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