DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I–V

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

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

SUMMARY: The following Agenda presents the results of the statutorily required semi-annual inventory of rulemaking actions currently under development within the U.S. Department of Health and Human Services. We hope that this information will enable interested members of the public to more effectively participate in the Department's regulatory activity.

FOR FURTHER INFORMATION CONTACT: Dawn L. Smalls, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: The information provided in the Agenda presents a forecast of the rulemaking activities that the Department of Health and Human Services (HHS) expects to undertake in the foreseeable future. Rulemakings are grouped according to pre-rulemaking actions, proposed rules, final rules, long-term actions, and rulemaking actions completed since the most recent Agenda was published on December 20, 2010. Please note that the actions included in this issue of the **Federal Register**, as required by the Regulatory Flexibility Act of 1980, relate only to those prospective rulemakings that are likely to have a significant economic impact on a substantial number of small entities.

Consistent with Executive Order 13563, the purpose of the Agenda is to encourage more effective public participation in the regulatory process. HHS invites all interested members of the public to comment on the rulemaking actions included in this issuance of the Agenda including comments on whether any of these or related rulemaking actions should be modified, streamlined, expanded, or repealed in order to make the agency's regulatory program more effective or less burdensome in achieving regulatory objectives. The complete Agenda is accessible online at *http://www.reginfo.gov* in an interactive format that offers users enhanced capabilities to obtain information from the Agenda's database.

Dated: April 4, 2011.

Dawn L. Smalls,

Executive Secretary, Department of Health and Human Services.

OFFICE OF THE SECRETARY—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
138	Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act.	0991–AB57

OFFICE OF CONSUMER INFORMATION AND INSURANCE OVERSIGHT—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
139	Status as a Grandfathered Health Plan Under the Affordable Care Act	0950–AA17

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
140	Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addiction (SECTION 610 REVIEW)	0930–AA14

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
141	Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth.	0930–AA10

CENTERS FOR DISEASE CONTROL AND PREVENTION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
142	Control of Communicable Diseases: Foreign and Possessions	0920–AA12
143	Control of Communicable Diseases: Interstate	0920–AA22

CENTERS FOR DISEASE CONTROL AND PREVENTION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
144	Quality Assurance Requirements for Respirators	0920–AA04

FOOD AND DRUG ADMINISTRATION—PRERULE STAGE

Sequence No.	Title	Regulation Identifier No.
145	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures (SECTION 610 REVIEW).	0910–AG14
146	Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents (SECTION 610 REVIEW).	0910–AG61
147	General Requirements for Blood, Blood Components, and Blood Derivatives; Donor Notification (SECTION 610 REVIEW).	0910–AG62

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
148	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics	0910–AC52
149	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
150	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40
151	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
152	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
153	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
154	Import Tolerances for Residues of Unapproved New Animal Drugs in Food	0910–AF78
155	Laser Products; Amendment to Performance Standard	0910–AF87
156	Pet Food Labeling Requirements	0910–AG09
157	Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding Animal Food	0910–AG10
158	Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products	0910–AG12
159	Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products	0910–AG18
160	Unique Device Identification	0910–AG31
161	Produce Safety Regulation	0910–AG35
162	Hazard Analysis and Risk-Based Preventive Controls	0910–AG36
163	''Tobacco Products'' Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act.	0910–AG38
164	General Hospital and Personal Use Devices: Issuance of Draft Special Controls Guidance for Infusion Pumps.	0910–AG54
165	Food Labeling: Nutrition Labeling for Food Sold in Vending Machines	0910–AG56
166	Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.	0910–AG57
167	Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives	0910–AG59
168	Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products.	0910–AG60

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
169	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors.	0910–AF27
170	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
171	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
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	Cigarette Warning Label Statements	0910–AG41

FOOD AND DRUG ADMINISTRATION—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
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	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53

FOOD AND DRUG ADMINISTRATION—LONG-TERM ACTIONS—Continued

Sequence No.	Title	Regulation Identifier No.
178	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling.	0910–AF11
179	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
180	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
181	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38

FOOD AND DRUG ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
182	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
183	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
184	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
185	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
186	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44
187	Over-the-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products	0910–AF51
188	Over-the-Counter (OTC) Drug Review—Antacid Products	0910–AF52
189	Over-the-Counter (OTC) Drug Review—Skin Bleaching Products	0910–AF53
190	Over-the-Counter (OTC) Drug Review—Stimulant Drug Products	0910–AF56
191	Over-the-Counter (OTC) Drug Review—Antidiarrheal Drug Products	0910–AF63
192	Over-the-Counter (OTC) Drug Review—Urinary Analgesic Drug Products	0910–AF70
193	Over-the-Counter (OTC) Drug Review—Certain Category II Active Ingredients	0910–AF95
194	Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution (SECTION 610 REVIEW).	0910–AG06

CENTERS FOR MEDICARE & MEDICAID SERVICES—PRERULE STAGE

Sequence No.	Title	Regulation Identifier No.
195	Five Year Review of Work Relative Value Units Under the Physician Fee Schedule (CMS–1582–PN)	0938–AQ87

CENTERS FOR MEDICARE & MEDICAID SERVICES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
196	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS–3819–P) (SECTION 610 REVIEW)	0938–AG81
197	Influenza Vaccination Standard for Certain Medicare Participating Providers and Suppliers (CMS–3213–P)	0938–AP92
198	Hospital Conditions of Participation: Requirements for Hospital Inpatient Psychiatric and Rehabilitation Units Excluded From the Prospective Payment System and LTCH Requirements (CMS–3177–P).	0938–AP97
199	Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and FY 2012 Rates and to the Long-Term Care Hospital PPS and FY 2012 Rates (CMS–1518–P).	0938–AQ24
200	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2012 (CMS–1525–P).	0938–AQ26
201	Changes to the ESRD Prospective Payment System for CY 2012 & Quality Incentives Program for CY 2013 (CMS–1577–P).	0938–AQ27
202	Medicaid Program Integrity: Registration of Billing Agents, Clearing Houses, or Other Alternate Payees (CMS–2365–P).	0938–AQ61
203	Medicaid Eligibility Expansion Under the Affordable Care Act of 2010 (CMS–2349–P)	0938–AQ62
204	Payments for Primary Care Services Under the Medicaid Program (CMS–2370–P)	0938–AQ63
205	Medicare and Medicaid Electronic Health Record Incentive Program—Stage 2 (CMS–0044–P)	0938–AQ84

CENTERS FOR MEDICARE & MEDICAID SERVICES—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
206	Enhanced Federal Funding for Medicaid Eligibility Determination and Enrollment Activities (CMS–2346–F)	0938–AQ53

CENTERS FOR MEDICARE & MEDICAID SERVICES—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
207	Requirements for Long-Term Care Facilities: Hospice Services (CMS–3140–F) (SECTION 610 REVIEW)	0938–AP32

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
208	Amendment to Payment Policies Under the Physician Fee Schedule and Part B for CY 2011 (CMS–1503–F2).	0938–AP79
209	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2011 (CMS–1504–FC).	0938–AP82
210	Section 508 Hospitals—Medicare and Medicaid Extenders Act of 2010 Changes (CMS–1357–N)	0938–AQ97

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office of the Secretary (OS)

Completed Actions

138. Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act

Legal Authority: Pub. L. 111–5, secs 13400 to 13410

Abstract: The Department of Health and Human Services, Office for Civil Rights, will issue rules to modify the HIPAA Privacy, Security, and Enforcement Rules as necessary to implement the privacy, security, and certain enforcement provisions of subtitle D of the Health Information Technology for Economic and Clinical Health Act (title XIII of the American Recovery and Reinvestment Act of 2009).

Timetable:

Action	Date	FR Cite
NPRM	07/14/10	75 FR 40867
NPRM Comment Period End.	09/13/10	
Merged With 0991–AB80.	03/02/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Andra Wicks, Privacy Specialist, Office of Civil Rights, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Phone: 202 205–2292, Fax: 202 205–4786, E-mail: *andra.wicks@hhs.gov*.

RIN: 0991–AB57

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office of Consumer Information and Insurance Oversight (OCIIO)

Completed Actions

139. Status as a Grandfathered Health Plan Under the Affordable Care Act

Legal Authority: Pub. L. 111–148

Abstract: The Affordable Care Act protects the ability of individuals and businesses to keep their current plan while providing important consumer protections. The new regulation also provides stability and flexibility to insurers and businesses that offer health insurance coverage as the nation transitions to a more competitive marketplace. In 2014, businesses and consumers will have more affordable choices through exchanges. This rule would finalize the requirements for group health plans and health insurance coverage in the group and individual markets and respond to any comments as the result of the interim final rule implementing this provision.

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/17/10	75 FR 34538
Interim Final Rule Effective.	07/12/10	
Interim Final Rule Comment Period End.	08/16/10	
Merged With 0938–AQ80.	02/11/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: James Mayhew, Director, Division of Market Rules Compliance Office, Department of Health and Human Services, Office of Consumer Information and Insurance Oversight, Mail Stop C2–12016, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–9244, E-mail: *james.mayhew@cms.hhs.gov*.

RIN: 0950–AA17

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Substance Abuse and Mental Health Services Administration (SAMHSA)

Final Rule Stage

140. Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addiction (Section 610 Review)

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

Abstract: This rule will amend the Federal opioid treatment program regulations. It will modify the dispensing requirements for buprenorphine and buprenorphine combination products that are approved by the Food and Drug Administration (FDA) for opioid dependence and used in federally certified and registered opioid treatment programs.

Timetable:

Action	Date	FR Cite
NPRM	06/19/09	74 FR 29153
NPRM Comment Period End.	08/18/09	
Final Action	12/00/11	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Nicholas Reuter, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Suite 2–1063, One Choke Cherry Road, Rockville, MD 20857, Phone: 240 276–2716, E-mail: *nicholas.reuter@samhsa.hhs.gov*.

RIN: 0930–AA14

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Substance Abuse and Mental Health Services Administration (SAMHSA)

Long-Term Actions

141. Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth

Legal Authority: Pub. L. 106–310, 42 U.S.C. 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, Associate Director for Consumer Affairs, 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, E-mail: *paolo.delvecchio@samhsa.hhs.gov.*

RIN: 0930–AA10

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention (CDC)

Final Rule Stage

142. Control of Communicable Diseases: Foreign and Possessions

Legal Authority: 42 U.S.C. 243; 42 U.S.C. 264 and 265; 42 U.S.C. 267 and 268; 42 U.S.C. 270 and 271

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. Communicable disease regulations are divided into two parts: Part 71 pertaining to foreign arrivals and part 70 pertaining to 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 final rule focuses primarily on requirements relating to the reporting of deaths and illnesses onboard aircrafts and ships, and the collection of specific traveler contact information for the purpose of CDC contacting travelers in the event of an exposure to a communicable disease.

Timetable:

Action	Date	FR Cite
NPRM	11/30/05	70 FR 71892
NPRM Comment Period End.	01/20/06	
Final Action	09/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Stacy Howard, Health Scientist, Department of Health and Human Services, Centers for Disease Control and Prevention, MS E–03, 1600 Clifton Road, NE., Atlanta, GA 30329, Phone: 404 498–1600, E-mail: *showard@cdc.gov.*

RIN: 0920–AA12

143. Control of Communicable Diseases: Interstate

Legal Authority: 28 U.S.C. 198; 28 U.S.C. 231; 25 U.S.C. 1661; 42 U.S.C. 243; 42 U.S.C. 248 and 249; 42 U.S.C. 264; 42 U.S.C. 266 to 268; 42 U.S.C. 270 to 272; 42 U.S.C. 2001

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. Communicable disease regulations are divided into two parts: Part 71 pertaining to foreign arrivals and part 70 pertaining to interstate matters. This rule (42 CFR Part 70) 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 proposed final rule focuses primarily on requirements relating to the reporting of deaths and illnesses onboard aircrafts, and the collection of specific traveler contact information for the purpose of CDC contacting travelers in the event of an exposure to a communicable disease.

Timetable:

Action	Date	FR Cite
NPRM	11/30/05	70 FR 71892
NPRM Comment Period End.	01/30/06	
Final Action	09/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Stacy Howard, Health Scientist, Department of Health and Human Services, Centers for Disease Control and Prevention, MS E–03, 1600 Clifton Road NE., Atlanta, GA 30329, Phone: 404 498–1600, E-mail: *showard@cdc.gov.*

RIN: 0920–AA22

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention (CDC)

Completed Actions

144. Quality Assurance Requirements for Respirators

Legal Authority: 29 U.S.C. 651 *et seq.;* 30 U.S.C. 3; 30 U.S.C. 5; 30 U.S.C. 7; 30 U.S.C. 811; 30 U.S.C. 842(h); 30 U.S.C. 844

Abstract: NIOSH plans to modify the Administrative/Quality Assurance sections of 42 CFR part 84, Approval of Respiratory Protective Devices. Areas for potential modification in this module are: (1) Upgrade of quality assurance requirements; (2) ability to use private sector quality auditors and private sector testing laboratories in the approval program; and (3) revised approval label requirements.

Timetable:

Action	Date	FR Cite
NPRM	12/10/08	73 FR 75045
NPRM Comment Period End.	02/09/09	
NPRM Comment Period Re-opened.	03/04/09	74 FR 9381
NPRM Comment Period Re-opened End.	04/10/09	
NPRM Comment Period Reopening Extended.	05/21/09	74 FR 23815
NPRM Comment Period End.	10/09/09	
Withdrawn	05/01/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: William E. Newcomb, Physical Scientist, Department of Health and Human Services, Centers for Disease Control and Prevention, PO Box 18070, 626 Cochran Mill Road, Pittsburgh, PA 15236, Phone: 412 386–5200, E-mail: *wnewcomb@cdc.gov.*

RIN: 0920–AA04

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Prerule Stage

145. Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures (Section 610 Review)

Legal Authority: 21 U.S.C. 331; 21 U.S.C. 333; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353; 21 U.S.C. 360; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 381

Abstract: Pursuant to section 610 of the Regulatory Flexibility Act, FDA is currently undertaking a review of regulations promulgated under the Prescription Drug Marketing Act (PDMA) including those contained in 21 CFR part 203 and 21 CFR 205.3 and 205.50 (as amended in 64 FR 67762 and 67763). The purpose of this review is to determine whether the regulations in 21 CFR part 203 and 21 CFR 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 statues, to minimize adverse impacts on a substantial number of small entities. FDA solicited comments on the following: (1) The continued need for the regulations in 21 CFR part 203 and 21 CFR 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 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 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 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 205.3 and 205.50 (as amended in 64 FR 67762 and 67763).

FDA received one comment on this review; and FDA notes that portions of the PDMA have been stayed in connection with RxUSA Wholesale, Inc., v. HHS, 467 F. Supp.2d 285 (E.D.N.Y. 2006), aff'd, 2008 U.S. App. LEXIS 14661 (2d Cir. 2008); and that the litigation itself has been administratively closed (with either party having the right to reopen) through June 30, 2011. FDA is certifying that it is not feasible for the agency to complete its review by December 4, 2010, and therefore is extending the completion date by one year.

Timetable:

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

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Howard Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6234, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, Phone: 301 796–3601, Fax: 301 847–8440, E-mail: *pdma610(c)review@fda.hhs.gov.*

RIN: 0910–AG14

146. • Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents (Section 610 Review)

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 360c and 360d; 21 U.S.C. 360h and 360i; 21 U.S.C. 371 and 372; 21 U.S.C. 374; 21 U.S.C. 381; 42 U.S.C. 216; 42 U.S.C. 262 to 264; 42 U.S.C. 263; 42 U.S.C. 263a; 42 U.S.C. 264

Abstract: FDA is undertaking a review of 21 CFR 610.40, 610.41, 610.42, 610.44, 640.67, 640.70, (as amended in 66 FR 31146) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in 21 CFR 610.40, 610.41, 610.42, 610.44, 640.67, 640.70 (as amended in 66 FR 31146) 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 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 of Current Regulation.	06/00/11	
End Review of Current Regulation.	12/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Melissa Reisman, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Suite 200N (HFM–17), 1401 Rockville Pike, Rockville, MD 20852, Phone: 301 827–6210.

RIN: 0910–AG61

147. • General Requirements for Blood, Blood Components, and Blood Derivatives; Donor Notification (Section 610 Review)

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 and 352; 21 U.S.C. 355; 21 U.S.C. 360 and 360j; 21 U.S.C. 371; 21 U.S.C. 374; 42 U.S.C. 216; 42 U.S.C. 262; 42 U.S.C. 263a; 42 U.S.C. 264; *et seq.*

Abstract: FDA is undertaking a review of 21 CFR 606.100(b), 606.160(b) and 630.6 (as amended in 66 FR 31165) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in 21 CFR 606.100(b), 606.160(b) and 630.6 (as amended in 66 FR 31165) 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 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	06/00/11	
End Review	12/00/11	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Melissa Reisman, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Suite 200N (HFM–17), 1401 Rockville Pike, Rockville, MD 20852, Phone: 301 827–6210.

RIN: 0910–AG62

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Proposed Rule Stage

148. Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics

Legal Authority: 21 U.S.C. 355; 21 U.S.C. 371; 42 U.S.C. 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.

Timetable:

Action	Date	FR Cite
NPRM	03/00/12	

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, WO 51, Room 6352, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, Phone: 301 796–3471, Fax: 301 847–8440, E-mail: *martha.nguyen@fda.hhs.gov.*

RIN: 0910–AC52

149. Over-the-Counter (OTC) Drug Review—Internal Analgesic Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 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 acetaminophen safety. The third action addresses products marketed for children under 2 years old and weight- and age-based dosing for children's products. The fourth action addresses combination products containing the analgesic acetaminophen or aspirin and sodium bicarbonate used as an antacid ingredient. 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	
Final Action (Required Warnings and Other Labeling).	04/29/09	74 FR 19385
Final Action (Correction).	06/30/09	74 FR 31177
Final Action (Technical Amendment).	11/25/09	74 FR 61512
NPRM (Acetaminophen).	04/00/12	
NPRM (Amendment) (Pediatric).	To Be Determined	
NPRM (Amendment) (Sodium Bicarbonate).	To Be Determined	
NPRM (Overindulgence/Hangover).	To Be Determined	
Final Action (Internal Analgesics).	To Be Determined	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov.*

RIN: 0910–AF36

150. Over-the-Counter (OTC) Drug Review—Oral Health Care Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360 to 360a; 21 U.S.C. 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 NPRM and final 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 (Benzocaine).	12/00/11	
NPRM (Plaque Gingivitis).	To Be Determined	
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Eng, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–2773, Fax: 301 796–9899, E-mail: *david.eng@fda.hhs.gov.*

RIN: 0910–AF40

151. Over-the-Counter (OTC) Drug Review—Sunscreen Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 finalizes

sunscreen labeling and testing requirements for both ultraviolet B and ultraviolet A radiation protection. The second action addresses other safety and effectiveness issues for OTC sunscreen drug products. The third action addresses active ingredients reviewed under Time and Extent Applications. The fourth action addresses the safety of sunscreen products. The last 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	
Final Action (UVA/UVB).	08/00/11	
NPRM (Safety and Effectiveness).	08/00/11	
NPRM (Time and Extent Applications).	04/00/12	
ANPRM (Safety)	06/00/12	
NPRM (Sunscreen and Insect Repellent).	To Be Determined	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Eng, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–2773, Fax: 301 796–9899, E-mail: *david.eng@fda.hhs.gov*.

RIN: 0910–AF43

152. Over-the-Counter (OTC) Drug Review—Weight Control Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 NPRM addresses the use of benzocaine for weight control. The first final action finalizes the 2005 proposed rule for weight control products containing phenylpropanolamine. The second final action will finalize the proposed rule for weight control products containing benzocaine.

Timetable:

Action	Date	FR Cite
NPRM (Phenylpropanolamine).	12/22/05	70 FR 75988
NPRM Comment Period End.	03/22/06	
NPRM (Benzocaine).	03/09/11	76 FR 12916
NPRM Comment Period End.	06/07/11	
Final Action (Phenylpropanolamine).	To Be Determined	
Final Action (Benzocaine).	To Be Determined	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Eng, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–2773, Fax: 301 796–9899, E-mail: *david.eng@fda.hhs.gov*.

RIN: 0910–AF45

153. Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 consumer products. The second action addresses testing requirements.

Timetable:

Action	Date	FR Cite
NPRM (Healthcare).	06/17/94	59 FR 31402
Comment Period End.	12/15/95	
NPRM (Consumer).	01/00/12	
NPRM (Food Handlers).	To Be Determined	
NPRM (Testing) ..	To Be Determined	
Final Action (Consumer).	To Be Determined	
Final Action (Testing).	To Be Determined	
Final Action (Food Handlers).	To Be Determined	
Final Action (First Aid Antiseptic).	To Be Determined	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Eng, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–2773, Fax: 301 796–9899, E-mail: *david.eng@fda.hhs.gov*.

RIN: 0910–AF69

154. Import Tolerances for Residues of Unapproved New Animal Drugs in Food

Legal Authority: 21 U.S.C. 342; 21 U.S.C. 360b(a)(6); 21 U.S.C. 371

Abstract: The Food and Drug Administration (FDA) plans to publish a proposed rule related to the implementation of the import tolerances provision of the Animal Drug Availability Act of 1996 (ADAA). The ADAA authorizes FDA to establish tolerances for unapproved new animal drugs where edible portions of animals imported into the United States may contain residues of such drugs (import tolerances). It is unlawful to import animal-derived food that bears or contains residues of a new animal drug that is not approved in the United States, unless FDA has established an import tolerance for that new animal drug and the residue of the new animal drug in the animal-derived food does not exceed that tolerance.

Timetable:

Action	Date	FR Cite
NPRM	09/00/11	
NPRM Comment Period End.	12/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Thomas Moskal, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Room 101, (MPN–4, HFV–232), 7519 Standish Place, Rockville, MD 20855, Phone: 240 276–9242, Fax: 240 276–9241, E-mail: *thomas.moskal@fda.hhs.gov*.

RIN: 0910–AF78

155. Laser Products; Amendment to Performance Standard

Legal Authority: 21 U.S.C. 360hh to 360ss; 21 U.S.C. 371; 21 U.S.C. 393

Abstract: FDA is proposing to amend the performance standard for laser products to achieve closer harmonization between the current standard and the International Electrotechnical Commission (IEC) standard for laser products and medical laser products. The proposed amendment is intended to update FDA's performance standard to reflect advancements in technology. The proposal would adopt portions of an IEC standard to achieve greater harmonization and reflect current science. In addition, the proposal would include an alternative mechanism for providing certification and identification, address novelty laser products, and clarify the military exemption for laser products.

Timetable:

Action	Date	FR Cite
NPRM	11/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Nancy Pirt, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 4438, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–6248, Fax: 301 847–8145, E-mail: *nancy.pirt@fda.hhs.gov*.

RIN: 0910–AF87

156. Pet Food Labeling Requirements

Legal Authority: 21 U.S.C. 343; 21 U.S.C. 371; Pub. L. 110–85, sec 1002(a)(3)

Abstract: The President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) on September 27, 2007 (Pub. L. 110–85). Title X of the FDAAA includes several provisions pertaining to food safety, including the safety of pet food. Section 1002(a)(3) of the new law directs FDA to issue new regulations to establish updated standards for the labeling of pet food that include nutritional and ingredient information. This same provision of the law also directs that, in developing these new regulations, FDA consult with the Association of American Feed Control Officials and other relevant stakeholder groups, including veterinary medical associations, animal health organizations, and pet food manufacturers.

Timetable:

Action	Date	FR Cite
NPRM	03/00/12	
NPRM Comment Period End.	06/00/12	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: William Burkholder, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Room 2642 (MPN–4, HFV–228), 7519 Standish Place, Rockville, MD 20855, Phone: 240 453–6865, E-mail: *william.burkholder@fda.hhs.gov*.

RIN: 0910–AG09

157. Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding Animal Food

Legal Authority: 21 U.S.C. 342; 21 U.S.C. 350e; 21 U.S.C. 371; 21 U.S.C. 374; 42 U.S.C. 264; Pub. L. 110–85, sec 1002(a)(2); Pub. L. 111–353

Abstract: The Food and Drug Administration (FDA) is proposing regulations for preventive 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. This action is also being taken to carry out the requirements of the Food and Drug Administration Amendments Act of 2007, under section 1002(a), and the Food Safety Modernization Act of 2010, under section 103.

Timetable:

Action	Date	FR Cite
NPRM	09/00/11	

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, Room 106 (MPN–4, HFV–230), 7519 Standish Place, Rockville, MD 20855, Phone: 240 276–9207, E-mail: *kim.young@fda.hhs.gov*.

RIN: 0910–AG10

158. Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products

Legal Authority: 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 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	12/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov*.

RIN: 0910–AG12

159. Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353; 21 U.S.C. 355; 21 U.S.C. 358; 21 U.S.C. 360; 21 U.S.C. 360b; 21 U.S.C. 360gg to 360ss; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 379e; 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 262; 42 U.S.C. 264

Abstract: This rule would require electronic package inserts for human drug and biological prescription products, in lieu of paper, which is currently used. These inserts contain prescribing information intended for healthcare practitioners. This would ensure that the information accompanying the product is the most up-to-date information regarding important safety and efficacy issues about these products.

Timetable:

Action	Date	FR Cite
NPRM	10/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Lisa Dwyer, Senior Advisor for Pharmacy Affairs, Department of Health and Human Services, Food and Drug Administration, Office of Policy, WO 32, Room 4253, 10903 New Hampshire Avenue, Silver Spring, MD 20993,

Phone: 301 796–4709, E-mail: *lisa.dwyer@fda.hhs.gov*.

RIN: 0910–AG18

160. Unique Device Identification

Legal Authority: Not Yet Determined

Abstract: The Food and Drug Administration Amendments Act of 2007 (FDAAA), amended the Federal Food, Drug, and Cosmetic Act by adding section 519(f) (21 U.S.C. 360i(f)). This section requires FDA to promulgate regulations establishing a unique identification system for medical devices requiring the label of medical devices to bear a unique identifier, unless FDA specifies an alternative placement or provides for exceptions. The unique identifier must adequately identify the device through distribution and use, and may include information on the lot or serial number.

Timetable:

Action	Date	FR Cite
NPRM	09/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: John J. Crowley, Senior Advisor for Patient Safety, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 2315, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 980–1936, E-mail: *jay.crowley@fda.hhs.gov*.

RIN: 0910–AG31

161. Produce Safety Regulation

Legal Authority: 21 U.S.C. 342; 21 U.S.C. 371; 42 U.S.C. 264; Pub. L. 111–353 (signed on January 4, 2011)

Abstract: The Food Safety Modernization Act requires the Secretary to establish and publish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death. FDA is proposing to promulgate regulations setting enforceable standards for fresh produce safety at the farm and packing house. The purpose of the proposed rule is to reduce the risk of illness associated with contaminated fresh produce. The proposed rule will be based on prevention-oriented public health principles and incorporate what we have learned in the past decade since the agency issued general good agricultural practice guidelines entitled ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables'' (GAPs Guide). The proposed rule also will reflect comments received on the agency's 1998 update of its GAPs guide and its July 2009 draft commodity specific guidances for tomatoes, leafy greens, and melons. Although the proposed rule will be based on recommendations that are included in the GAPs guide, FDA does not intend to make the entire guidance mandatory. FDA's proposed rule would, however, set out clear standards for implementation of modern preventive controls. The proposed rule also would emphasize the importance of environmental assessments to identify hazards and possible pathways of contamination and provide examples of risk reduction practices recognizing that operators must tailor their preventive controls to particular hazards and conditions affecting their operations. The requirements of the proposed rule would be scale appropriate and commensurate with the relative risks and complexity of individual operations. FDA intends to issue guidance to assist industry in complying with the requirements of the new regulation.

Timetable:

Action	Date	FR Cite
NPRM	01/00/12	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Samir Assar, Supervisory Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Safety, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: 301 436–1636, E-mail: *samir.assar@fda.hhs.gov*.

RIN: 0910–AG35

162. Hazard Analysis and Risk-Based Preventive Controls

Legal Authority: 21 U.S.C. 342; 21 U.S.C. 371; 42 U.S.C. 264; Pub. L. 111–353, (signed on January 4, 2011)

Abstract: The Food and Drug Administration (FDA) Food Safety Modernization Act (the FSMA) requires the Secretary of Health and Human Services to promulgate regulations to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls; and to define the terms 'small business' and 'very small business.' The FSMA also requires the Secretary to promulgate regulations with respect to activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on a farm or another farm under the same ownership and activities that constitute on farm manufacturing or processing of food that is not grown, raised, or consumed on a farm or another farm under the same ownership.

FDA is proposing to amend its current good manufacturing practice (CGMP) regulations (21 CFR Part 110) for manufacturing, packing, or holding human food to require food facilities to develop and implement a written food safety plan. This proposed rule would require a food facility to have and implement preventive controls to significantly minimize or prevent the occurrence of hazards that could affect food manufactured, processed, packed, or held by the facility and to provide assurances that such food will not be adulterated under section 402 or misbranded under section 403(w).

Timetable:

Action	Date	FR Cite
NPRM	10/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: John F. Sheehan, Director, Office of Food Safety, Division of Plant and Dairy Food Safety, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–315), Office of Food Safety, 5100 Paint Branch Parkway, College Park, MD 20740, Phone: 301 436–1488, Fax: 301 436–2632, E-mail: *john.sheehan@fda.hhs.gov*.

RIN: 0910–AG36

163. ''Tobacco Products'' Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act

Legal Authority: 21 U.S.C. 301 *et seq.,* The Federal Food, Drug, and Cosmetic Act; Pub. L. 111–31, The Family Smoking Prevention and Tobacco Control Act

Abstract: The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. Section 901 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, permits FDA to issue regulations deeming other tobacco

products to be subject to the FD&C Act. This proposed rule would deem products meeting the statutory definition of ''tobacco product'' found at section 201(rr) of the FD&C Act to be subject to FDA's jurisdiction. The scope of the proposed rule deeming cigars to be subject to FDA's jurisdiction that was previously included in the Unified Agenda is being broadened to encompass products that meet the statutory definition of ''tobacco product.''

Timetable:

Action	Date	FR Cite
NPRM	10/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: May Nelson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20850, Phone: 877 287–1373, Fax: 240 276–3904, E-mail: *may.nelson@fda.hhs.gov*.

RIN: 0910–AG38

164. General Hospital and Personal Use Devices: Issuance of Draft Special Controls Guidance for Infusion Pumps

Legal Authority: 21 U.S.C. 351; 21 U.S.C. 360; 21 U.S.C. 360c; 21 U.S.C. 360e; 21 U.S.C. 360j; 21 U.S.C. 371

Abstract: Since 2003, FDA has seen a dramatic increase in the number of device recalls, as well as an increase in the number of death and serious injury reports submitted regarding infusion pumps. An analysis of the reports reveals that a majority of the recalls and failures were caused by user error and/or device design flaw. As a result of these incidents, FDA is proposing to issue a draft special controls guidance document that, when final, will be a special control for infusion pumps. The agency believes that establishing these special controls for infusion pumps is necessary to provide reasonable assurance of the safety and effectiveness of these devices.

Timetable:

Action	Date	FR Cite
NPRM	09/00/11	
NPRM Comment Period End.	12/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Nancy Pirt, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66 Room 4438, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–6248, Fax: 301 847–8145, E-mail: *nancy.pirt@fda.hhs.gov*.

RIN: 0910–AG54

165. Food Labeling: Nutrition Labeling for Food Sold in Vending Machines

Legal Authority: 21 U.S.C. 343; 21 U.S.C. 371

Abstract: The Food and Drug Administration (FDA) is proposing regulations to establish requirements for nutrition labeling of certain food sold in certain vending machines. FDA is also proposing the terms and conditions for vending machine operators registering to voluntarily be subject to the requirements of section 4205. FDA is taking this action to carry out section 4205 of the Patient Protection and Affordable Care Act (''Affordable Care Act'' or ''ACA''), which was signed into law on March 23, 2010.

Timetable:

Action	Date	FR Cite
NPRM	04/06/11	76 FR 19238
NPRM Comment Period End.	07/05/11	

Regulatory Flexibility Analysis Required: Yes.

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, Fax: 301 436–2636, E-mail: *geraldine.june@fda.hhs.gov*.

RIN: 0910–AG56

166. Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

Legal Authority: 21 U.S.C. 343; 21 U.S.C. 371

Abstract: The Food and Drug Administration (FDA) is proposing regulations to establish requirements for nutrition labeling of standard menu items in chain restaurants and similar retail food establishments. FDA is also proposing the terms and conditions for restaurants and similar retail food establishments registering to voluntarily be subject to the requirements of section 4205. FDA is taking this action to carry out section 4205 of the Patient Protection and Affordable Care Act (''Affordable Care Act'' or ''ACA''), which was signed into law on March 23, 2010.

Timetable:

Action	Date	FR Cite
NPRM	04/06/11	76 FR 19192
NPRM Comment Period End.	06/06/11	

Regulatory Flexibility Analysis Required: Yes.

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, Fax: 301 436–2636, E-mail: *geraldine.june@fda.hhs.gov*.

RIN: 0910–AG57

167. • Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives

Legal Authority: Pub. L. 111–31, The Family Smoking Prevention and Tobacco Control Act, sec 101(b)

Abstract: Section 915 of the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, requires FDA to promulgate regulations that require the testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents that the agency determines should be tested to protect the public health.

Timetable:

Action	Date	FR Cite
NPRM	01/00/12	
NPRM Comment Period End.	04/00/12	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Rm 240 H, 9200 Corporate Boulevard, Rockville, MD 20850, Phone: 877 287–1373, Fax: 240 276–3904, E-mail: *carol.drew@fda.hhs.gov*.

RIN: 0910–AG59

168. • Further Amendments to General Regulations of the Food and Drug Administration To Incorporate Tobacco Products

Legal Authority: Not Yet Determined

Abstract: The Food and Drug Administration is seeking to amend certain of its general regulations to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Family Smoking Prevention and

Tobacco Control Act. The proposed rule would cover revisions to the document reporting requirements and definition of ''product.''

Timetable:

Action	Date	FR Cite
NPRM	04/14/11	76 FR 20901
NPRM Comment Period End.	06/13/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Gerie Voss, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20850, Phone: 877 287–1373, Fax: 240 276–4193, E-mail: *gerie.voss@fda.hhs.gov*.

RIN: 0910–AG60

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Final Rule Stage

169. Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 350a; 21 U.S.C. 371

Abstract: The Food and Drug Administration (FDA) is revising its infant formula regulations in 21 CFR parts 106 and 107 to establish requirements for current good manufacturing practices (CGMP), including audits; to establish requirements for quality factors; and to amend FDA's quality control procedures, notification, and record and reporting requirements for infant formula. FDA is taking this action to improve the protection of infants who consume infant formula products.

Timetable:

Action	Date	FR Cite
NPRM	07/09/96	61 FR 36154
NPRM Comment Period End.	12/06/96	
NPRM Comment Period Reopened.	04/28/03	68 FR 22341
NPRM Comment Period Extended.	06/27/03	68 FR 38247
NPRM Comment Period End.	08/26/03	
NPRM Comment Period Reopened.	08/01/06	71 FR 43392
NPRM Comment Period End.	09/15/06	
Final Action	11/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Benson Silverman, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–850), 5100 Paint Branch Parkway, College Park, MD 20740, Phone: 301 436–1459, E-mail: *benson.silverman@fda.hhs.gov*.

RIN: 0910–AF27

170. Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 labeling for single ingredient bronchodilator products.

Timetable:

Action	Date	FR Cite
NPRM (Amendment—Ephedrine Single Ingredient).	07/13/05	70 FR 40237
NPRM Comment Period End.	11/10/05	
Final Action (Technical Amendment).	11/30/07	72 FR 67639
Final Action (Amendment—Single Ingredient Labeling).	06/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov*.

RIN: 0910–AF32

171. Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 cough/cold drug products containing an oral bronchodilator (ephedrine and its salts) in combination with any expectorant or any oral nasal decongestant.

Timetable:

Action	Date	FR Cite
NPRM (Amendment).	07/13/05	70 FR 40232
NPRM Comment Period End.	11/10/05	
Final Action (Technical Amendment).	03/19/07	72 FR 12730
Final Action	03/00/12	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov*.

RIN: 0910–AF33

172. Use of Materials Derived From Cattle in Human Food and Cosmetics

Legal Authority: 21 U.S.C. 342; 21 U.S.C. 361; 21 U.S.C. 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.

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	09/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Amber McCoig, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFS–316), 5100 Paint Branch Parkway, College Park, MD 20740, Phone: 301 436–2131, Fax: 301 436–2644, E-mail: *amber.mccoig@fda.hhs.gov*.

RIN: 0910–AF47

173. Label Requirement for Food That Has Been Refused Admission Into the United States

Legal Authority: 15 U.S.C. 1453 to 1455; 21 U.S.C. 321; 21 U.S.C. 342 and 343; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 381; 42 U.S.C. 216; 42 U.S.C. 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	07/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Daniel Sigelman, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, WO Building 1, Room 4245, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–4706, E-mail: *daniel.sigelman@fda.hhs.gov*.

RIN: 0910–AF61

174. Cigarette Warning Label Statements

Legal Authority: Pub. L. 111–31, The Family Smoking Prevention and Tobacco Control Act, sec 201

Abstract: Section 4 of the FCLAA, as amended by section 201 of the Tobacco Control Act, requires FDA to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany required warning statements on cigarette packages and advertisements. FDA also may adjust the type size, text and format of the required label statements on product packaging and advertising if FDA determines that it is appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.

Timetable:

Action	Date	FR Cite
NPRM	11/12/10	75 FR 69524
NPRM Comment Period End.	01/11/11	
Final Action	06/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Gerie Voss, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20850, Phone: 877 287–1373, Fax: 240 276–4193, E-mail: *gerie.voss@fda.hhs.gov*.

RIN: 0910–AG41

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 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 242a; 42 U.S.C. 262 and 263; 42 U.S.C. 263a to 263n; 42 U.S.C. 264; 42 U.S.C. 300aa; 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 360b to 360j; 21 U.S.C. 361a; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 375; 21 U.S.C. 379e; 21 U.S.C. 381

Abstract: The final rule would amend the postmarketing 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. These revisions were proposed as part of a single rulemaking (68 FR 12406) to clarify and revise both premarketing and postmarketing safety reporting requirements for human drug and biological products. FDA plans to finalize the premarket and postmarket safety reporting requirements in separate final rules. Premarketing safety reporting requirements were finalized in a separate final rule published on September 29, 2010 (75 FR 59961). This final rule applies to postmarketing safety reporting requirements.

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.

Agency Contact: Jane E. Baluss, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room

6362, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, Phone: 301 796–3469, Fax: 301 847–8440, E-mail: *jane.baluss@fda.hhs.gov.*

RIN: 0910–AA97

176. Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 342; 21 U.S.C. 343; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 381; 21 U.S.C. 393; 42 U.S.C. 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. FDA also published an Interim Final Rule in the same **Federal Register** (72 FR 34959) that provided a procedure for requesting an exemption from the final rule requirement 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 Rule	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.

Agency Contact: Linda Kahl, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–024), 5100 Paint Branch Parkway, College Park, MD 20740, Phone: 301 436–2784, Fax: 301 436–2657, E-mail: *linda.kahl@fda.hhs.gov.*

RIN: 0910–AB88

177. Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 351 to 21 U.S.C. 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 accidents, do not occur in the future. FDA has described a number of proposals in the proposed rule including requiring that gas use outlet connections on portable cryogenic medical gas containers be securely attached to the valve body.

Timetable:

Action	Date	FR Cite
NPRM	04/10/06	71 FR 18039
NPRM Comment Period End.	07/10/06	
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Patrick Raulerson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6368, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, Phone: 301 796–3522, Fax: 301 847–8440, E-mail: *patrick.raulerson@fda.hhs.gov*.

RIN: 0910–AC53

178. Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 358; 21 U.S.C. 360; 21 U.S.C. 360b; 21 U.S.C. 360gg to 360ss; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 379e; 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 262; 42 U.S.C. 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). Under FDA's current regulations, labeling concerning the use of prescription drugs in pregnancy uses letter categories (A, B, C, D, X) to characterize the risk to the fetus of using the drug in pregnancy. One of the deficiencies of the category system is that drugs may be assigned to the same category when the severity, incidence, and types of risk are quite different. Dissatisfaction with the category system has been expressed by health care providers, medical organizations, experts in the study of birth defects, women's health researchers, and women of childbearing age. Stakeholders consulted through a public hearing, several focus groups, and several advisory committees have recommended that FDA replace the category system with a concise narrative summarizing a product's risks to pregnant women and to women of childbearing age. Therefore, the revised format and the information provided in the labeling would make it easier for health care providers to understand the risks and benefits of drug use during pregnancy and lactation.

Timetable:

Action	Date	FR Cite
NPRM	05/29/08	73 FR 30831
NPRM Comment Period End.	08/27/08	
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Rachel S. Bressler, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation Research, WO 51, Room 6224, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, Phone: 301 796–4288, Fax: 301 847–8440, E-mail: *rachel.bressler@fda.hhs.gov*.

RIN: 0910–AF11

179. Over-The-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 antihistamine labeling claims for the common cold.

Timetable:

Action	Date	FR Cite
Reopening of Administrative Record.	08/25/00	65 FR 51780
Comment Period End.	11/24/00	
NPRM (Amendment) (Common Cold).	08/00/12	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov.*

RIN: 0910–AF31

180. Over-the-Counter (OTC) Drug Review—External Analgesic Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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).	06/00/12	
NPRM (Amendment).	To Be Determined	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Eng, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–2773, Fax: 301 796–9899, E-mail: *david.eng@fda.hhs.gov.*

RIN: 0910–AF35

181. Over-the-Counter (OTC) Drug Review—Laxative Drug Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360 to 360a; 21 U.S.C. 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 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. The final action will address laxative drug products.

Timetable:

Action	Date	FR Cite
Final Action (Granular Psyllium).	03/29/07	72 FR 14669
NPRM (Professional Labeling—Sodium Phosphate).	02/11/11	76 FR 7743
NPRM Comment Period End.	03/14/11	
NPRM (Professional Labeling).	To Be Determined	
Final Action (Laxative Drug Products).	To Be Determined	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov.*

RIN: 0910–AF38

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Completed Actions

182. Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 phenylpropanolamine.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Sinusitis Claim).	08/02/04	69 FR 46119
NPRM Comment Period End.	11/01/04	
NPRM (Phenylephrine Bitartrate).	11/02/04	69 FR 63482
NPRM Comment Period End.	01/31/05	
NPRM (Phenylpropanolamine).	12/22/05	70 FR 75988
NPRM Comment Period End.	03/22/06	
Final Action (Amendment) (Sinusitis Claim).	10/31/05	70 FR 58974
Final Action (Phenylephrine Bitartrate).	08/01/06	71 FR 83358
Withdrawn	03/11/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov.*

RIN: 0910–AF34

183. Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 358; 21 U.S.C. 360; 21 U.S.C. 371; 21 UCS 374; 21 U.S.C. 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
NPRM Comment Period End.	04/11/07	
Withdrawn	03/11/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov.*

RIN: 0910–AF37

184. Over-the-Counter (OTC) Drug Review—Ophthalmic Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 finalizes the monograph for emergency first aid eyewash drug products.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Emergency First Aid Eyewashes).	02/19/03	68 FR 7917
NPRM Comment Period End.	05/20/03	
Withdrawn	03/11/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov.*

RIN: 0910–AF39

185. Over-the-Counter (OTC) Drug Review—Skin Protectant Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 identifies safe and effective skin protectant active ingredients to treat and prevent diaper rash. The second action addresses skin protectant products used to treat fever blisters and cold sores.

Timetable:

Action	Date	FR Cite
Final Action (Technical Amendments).	02/01/08	73 FR 6014
Final Action (Aluminum Acetate) (Technical Amendment).	03/06/09	74 FR 9759
Withdrawn	03/11/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Eng, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–2773, Fax: 301 796–9899, E-mail: *david.eng@fda.hhs.gov.*

RIN: 0910–AF42

186. Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 358; 21 U.S.C. 360; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 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 proposed rule addresses vaginal contraceptive drug products.

Timetable:

Action	Date	FR Cite
Final Action (Warnings).	12/19/07	72 FR 71769
Withdrawn	03/11/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov.*

RIN: 0910–AF44

187. Over-the-Counter (OTC) Drug Review—Overindulgence In Food and Drink Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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
NPRM Comment Period End.	04/05/05	
Withdrawn	03/11/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov.*

RIN: 0910–AF51

188. Over-the-Counter (OTC) Drug Review—Antacid Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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
Withdrawn	03/11/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov*.

RIN: 0910–AF52

189. Over-the-Counter (OTC) Drug Review—Skin Bleaching Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 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	
Withdrawn	03/11/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Eng, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–2773, Fax: 301 796–9899, E-mail: *david.eng@fda.hhs.gov*.

RIN: 0910–AF53

190. Over-the-Counter (OTC) Drug Review—Stimulant Drug Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 use of stimulant active ingredients to relieve symptoms associated with a hangover.

Timetable:

Action	Date	FR Cite
Withdrawn	03/11/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov*.

RIN: 0910–AF56

191. Over-the-Counter (OTC) Drug Review—Antidiarrheal Drug Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371

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

Timetable:

Action	Date	FR Cite
Withdrawn	03/11/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov*.

RIN: 0910–AF63

192. Over-the-Counter (OTC) Drug Review—Urinary Analgesic Drug Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 products used for urinary pain relief.

Timetable:

Action	Date	FR Cite
Withdrawn	03/11/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–0260, Fax: 301 796–9899, E-mail: *mary.chung@fda.hhs.gov*.

RIN: 0910–AF70

193. Over-the-Counter (OTC) Drug Review—Certain Category II Active Ingredients

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371

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 issued 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 rule will finalize the 2008 proposed rule.

Timetable:

Action	Date	FR Cite
NPRM	06/19/08	73 FR 34895
NPRM Comment Period End.	09/17/08	
Withdrawn	03/11/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Eng, Department of Health and Human Services, Food and Drug Administration, Center for Drug

Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: 301 796–2773, Fax: 301 796–9899, E-mail: *david.eng@fda.hhs.gov*.

RIN: 0910–AF95

194. Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution (Section 610 Review)

Legal Authority: 15 U.S.C. 1453 to 1455; 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 342 and 343; 21 U.S.C. 348; 21 U.S.C. 371; 42 U.S.C. 243; 42 U.S.C. 264; 42 U.S.C. 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) (21 CFR 16.5(a)(4)) provides that part 16 does not apply to a hearing on an order for relabeling, diversion, or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and §§ 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, provided the words ''keep refrigerated'' appear on the principal display panel or information panel. FDA is undertaking a review of 21 CFR 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 §§ 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	12/15/09	
End Review	12/30/10	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Geraldine A. June, Supervisor, Product Evaluation and Labeling Team, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFS–820), 5100 Paint Branch Parkway, College Park, MD 20740, Phone: 301 436–1802, Fax: 301 436–2636, E-mail: *geraldine.june@fda.hhs.gov*.

RIN: 0910–AG06

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Prerule Stage

195. • Five Year Review of Work Relative Value Units Under the Physician Fee Schedule (CMS–1582–PN)

Legal Authority: SSA, sec 1848(c)(2)(B)(i)

Abstract: This proposed notice sets forth proposed revisions to work relative value units (RVUs) affecting payment for physicians' services. The Act requires that we review RVUs no less than every five years. The revised values will be finalized in the CY 2012 Physician Fee Schedule final rule and will be effective for services furnished beginning January 1, 2012.

Timetable:

Action	Date	FR Cite
Notice	06/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Rebecca Cole, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop: C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–1589, E-mail: *rebecca.cole@cms.hhs.gov*.

RIN: 0938–AQ87

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

196. Home Health Agency (HHA) Conditions of Participation (COPS) (CMS–3819–P) (Section 610 Review)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395x; 42 U.S.C. 1395cc(a); 42 U.S.C. 1395hh; 42 U.S.C. 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 CoPs were last revised in 1989. The new requirements will focus on the actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our efforts to achieve broad-based improvements and measurements of the quality of care furnished through federal programs while at the same time reducing procedural burdens on providers.

Timetable:

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End.	06/09/97	
Second NPRM	09/00/11	

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 & Quality, Mail Stop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–6617, E-mail: *danielle.shearer@cms.hhs.gov*.

RIN: 0938–AG81

197. Influenza Vaccination Standard for Certain Medicare Participating Providers and Suppliers (CMS–3213–P)

Legal Authority: Social Security Act secs 1881, 1861, 1102, 1871

Abstract: This proposed rule would require certain Medicare and Medicaid providers and suppliers to offer all patients an annual influenza vaccination, unless medically contraindicated or unless the patient or patient's representative or surrogate declined vaccination. This proposed rule is intended to increase the number of patients receiving annual vaccination against seasonal influenza and to

decrease the morbidity and mortality rate from influenza. This proposed rule would also require certain providers and suppliers to develop policies and procedures that would allow them to offer vaccinations for pandemic influenza in case of a future pandemic influenza event for which a vaccine may be developed.

Timetable:

Action	Date	FR Cite
NPRM	06/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Lauren Oviatt, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–4683, E-mail: *lauren.oviatt@cms.hhs.gov*.

RIN: 0938–AP92

198. Hospital Conditions of Participation: Requirements for Hospital Inpatient Psychiatric and Rehabilitation Units Excluded From the Prospective Payment System and Ltch Requirements (CMS–3177–P)

Legal Authority: 42 U.S.C. 1385 X; 42 U.S.C. 1396 d; 42 U.S.C. 1395 hh

Abstract: This rule proposes requirements for inpatient psychiatric units and inpatient rehabilitation facilities under the hospital conditions of participation (CoPs). This would allow accrediting organizations to deem these units as part of their hospital accreditation process providing a timely and cost effective survey and certification process under the CoPs. In addition, this rule would propose long term care hospital requirements mandated by the Medicare, Medicaid and SCHIP Extension Act of 2007.

Timetable:

Action	Date	FR Cite
NPRM	09/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Capt. Katherine Berkhousen, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S3–02–01, Baltimore, MD 21244, Phone: 410 786–1154, E-mail: *katherine.berkhousen@cms.hhs.gov*.

Jeannie Miller, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–3164, E-mail: *jeannie.miller@cms.hhs.gov*.

RIN: 0938–AP97

199. Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and FY 2012 Rates and to the Long-Term Care Hospital PPS and FY 2012 Rates (CMS–1518–P)

Legal Authority: sec 1886(d) of the Social Security Act; Pub. L. 111–148

Abstract: This annual major proposed rule would revise the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This proposed rule would implement changes arising from our continuing experience with these systems.

Timetable:

Action	Date	FR Cite
NPRM	06/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: AnKit Patel, Health Insurance Specialist, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Hospital and Ambulatory Policy Group, Mail Stop, C4–25–11, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–4537, E-mail: *ankit.patel@cms.hhs.gov*.

RIN: 0938–AQ24

200. Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2012 (CMS–1525–P)

Legal Authority: Social Security Act, sec 1833; Pub. L. 111–148

Abstract: This proposed 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. The proposed rule also describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule proposes changes to the Ambulatory Surgical Center Payment System list of services and rates.

Timetable:

Action	Date	FR Cite
NPRM	07/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Paula Smith, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop, C5–01–26, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–7809, E-mail: *paula.smith@cms.hhs.gov*.

RIN: 0938–AQ26

201. Changes to the ESRD Prospective Payment System For Cy 2012 & Quality Incentives Program For CY 2013 (CMS–1577–P)

Legal Authority: Sec 1881 of the Social Security Act

Abstract: This major proposed rule would update the bundled payment system for End Stage Renal Disease (ESRD) facilities by January 1, 2012. The rule would also update the Quality Incentives in the ESRD Program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janet Samen, Director, Division of Chronic Care Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C5–05–27, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–4533, E-mail: *janet.samen@cms.hhs.gov*.

RIN: 0938–AQ27

202. • Medicaid Program Integrity: Registration Of Billing Agents, Clearing Houses, Or Other Alternate Payees (CMS–2365–P)

Legal Authority: 42 U.S.C. 1396a(a)(79) Social Security Act; Pub. L. 111–148, sec 6503

Abstract: This proposed rule would require any agent, clearinghouse, or other alternate payee that submits claims on behalf of a health care provider to register with the State and the Secretary in a form and manner specified by the Secretary.

Timetable:

Action	Date	FR Cite
NPRM	10/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Richard Friedman, Director, Division of State Systems, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop S3–18–13, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–4451, E-mail: *richard.friedman@cms.hhs.gov*.

RIN: 0938–AQ61

203. • Medicaid Eligibility Expansion Under the Affordable Care Act of 2010 (CMS–2349–P)

Legal Authority: Pub. L. 111–148, secs 1413, 2001, 2002, 2201

Abstract: The Affordable Care Act authorizes a major Medicaid expansion to individuals who are under 65, not pregnant, not receiving Medicare and not eligible for other mandatory eligibility categories. This proposed rule would set forth policies for Medicaid expansion including household income and household composition, coordination with Exchanges, simplifying and streamlining Medicaid eligibility determinations.

Timetable:

Action	Date	FR Cite
NPRM	06/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Sarah DeLone, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop S2–01–16, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–0615, E-mail: *sarah.delone@cms.hhs.gov*.

RIN: 0938–AQ62

204. • Payments for Primary Care Services Under the Medicaid Program (CMS–2370–P)

Legal Authority: Pub. L. 111–152, sec 1202

Abstract: This regulation implements section 1202 of the Health Care and Education Reconciliation Act of 2010, which increases Medicaid payments for certain primary care services provided in 2013 and 2014. The increased payments pertain to services provided by a physician with a specialty designation of family medicine, general internal medicine, and pediatric medicine. States must pay for these services at a rate equal to or greater than the rate paid under Medicare Part B. Rates in Medicaid managed care must be consistent with these minimum payment rates. The FMAP to states for such services will equal 100% for the portion of cost for such primary care services, which is comprised of the difference between the Medicare Part B rate and the amount applicable in the State Plan as of July 1, 2009.

Timetable:

Action	Date	FR Cite
NPRM	10/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Cherly Powell, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop S2–01–16, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–9239, E-mail: *cherly.powell@cms.hhs.gov*.

RIN: 0938–AQ63

205. • Medicare and Medicaid Electronic Health Record Incentive Program—Stage 2 (CMS–0044–P)

Legal Authority: Pub. L. 111–5 secs 4101, 4102, and 4202

Abstract: The final rule for the Medicare and Medicaid EHR Incentive Programs, which was published in the **Federal Register** on July 28, 2010, specifies that CMS will expand on the criteria for meaningful use established for Stage 1 to advance the use of certified EHR technology by eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs). This proposed rule would establish the requirements for Stage 2. As stated in the July 28 final rule, ''Our goals for the Stage 2 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, expand upon the Stage 1 criteria to encourage the use of health IT for continuous quality improvement at the point of care and the exchange of information in the most structured format possible, such as the electronic transmission of orders entered using computerized provider order entry (CPOE) and the electronic transmission of diagnostic test results.''

Timetable:

Action	Date	FR Cite
NPRM	01/00/12	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Elizabeth Holland, Director, Health Initiatives Group/Office of e–Health Standards and Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–1309, E-mail: *elizabeth.holland@cms.hhs.gov*.

RIN: 0938–AQ84

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Final Rule Stage

206. Enhanced Federal Funding For Medicaid Eligibility Determination and Enrollment Activities (CMS–2346–F)

Legal Authority: Pub. L. 111–148, sec 1413

Abstract: The Affordable Care Act requires States' residents to apply, enroll, receive determinations, and participate in the State health subsidy programs known as ''the Exchange''. The Affordable Care Act requires many changes to State eligibility and enrollment systems and each State is responsible for developing a secure, electronic interface allowing the exchange of data. Existing legacy eligibility systems are not able to implement the numerous requirements. This rule is key to informing States about the higher rates that CMS will provide to help them update or build legacy eligibility systems that meet the ACA requirements.

Timetable:

Action	Date	FR Cite
NPRM	11/08/10	75 FR 68583
NPRM Comment Period End.	01/07/11	
Final Action	06/00/11	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Richard H. Friedman, Director, Division of State Systems, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop S3–18–13, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–4451, E-mail: *richard.friedman@cms.hhs.gov*.

RIN: 0938–AQ53

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Long-Term Actions

207. Requirements for Long-Term Care Facilities: Hospice Services (CMS–3140–F) (Section 610 Review)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This rule establishes that in order to participate in the Medicare and Medicaid programs, long-term care facilities must have an agreement with hospice agencies when hospice care is

provided in a long-term care facility. The rule also contains quality of care requirements.

Timetable:

Action	Date	FR Cite
NPRM	10/22/10	75 FR 65282
NPRM Comment Period End.	12/21/10	
Final Action	10/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kadie Thomas, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Mail Stop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–0468, E-mail: *kadie.thomas@cms.hhs.gov*.

Mary Collins, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Mail Stop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–3189, E-mail: *mary.collins@cms.hhs.gov*.

RIN: 0938–AP32

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Completed Actions

208. Amendment to Payment Policies Under the Physician Fee Schedule and Part B for CY 2011 (CMS–1503–F2)

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1871; Pub. L. 111–148

Abstract: This amends the ''Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011'' that appeared in the November 29, 2010, **Federal Register**.

Timetable:

Action	Date	FR Cite
NPRM	07/13/10	75 FR 40040
NPRM Comment Period End.	09/24/10	
Final Action	11/29/10	75 FR 73169
2nd Final Action ..	01/10/11	76 FR 1366

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Carol Bazell, Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–6960, E-mail: *carol.bazell@cms.hhs gov*.

RIN: 0938–AP79

209. Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System For CY 2011 (CMS–1504–FC)

Legal Authority: sec 1833 of the Social Security Act; BBA, BA, BIPA, MMA, Pub. L. 111.148

Abstract: This final rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. The rule also describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule changes the Ambulatory Surgical Center Payment System list of services and rates.

Timetable:

Action	Date	FR Cite
NPRM	08/03/10	75 FR 46169
NPRM Comment Period End.	08/31/10	
Final Action	11/24/10	75 FR 71800

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Alberta Dwivedi, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C5–01–26, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–0763, E-mail: *alberta.dwivedi@cms.hhs.gov*.

RIN: 0938–AP82

210. • Section 508 Hospitals—Medicare and Medicaid Extenders Act of 2010 Changes (CMS–1357–N)

Legal Authority: MMEA, Sec 102

Abstract: Section 102 of the Medicare and Medicaid Extenders Act of 2010 extends section 508 of the Medicare Modernization Act of 2003 (MMA) and certain additional special exception hospital reclassifications from October 1, 2010, through September 30, 2011. Effective April 1, 2011, section 102 also requires removing section 508 and special exception hospitals' wage data from the calculation of the reclassified wage index if doing so raises the reclassified wage index. All hospitals affected by section 102 will be assigned an individual special wage index effective April 1, 2011. If the section 508 or special exception hospital's wage index applicable for the period beginning on October 1, 2010, and ending on March 31, 2011, is lower than for the period beginning on April 1, 2011, and ending on September 30, 2011, the hospital will be paid an additional amount that reflects the difference between the wage indices. The provision applies to both inpatient and outpatient hospital payments, although the implementation timeframe differs for outpatient hospital payments.

Timetable:

Action	Date	FR Cite
Notice	04/07/11	76 FR 19365

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Brian Slater, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–5229, E-mail: *brian.slater@cms.hhs.gov*.

RIN: 0938–AQ97

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Part IX

Department of Homeland Security

Semiannual Regulatory Agenda