Federal Register

Monday,
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Part V

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

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

Regulatory Agenda

AGENCY: Office of the Secretary, HHS

ACTION: Semiannual Regulatory Agenda

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order (EO) 12866 require the semi-annual issuance of an inventory of rulemaking actions under development throughout the Department, with a view to offering for public review, at as early a stage as possible, summarized information about forthcoming regulatory actions.

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

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

Please note that the rulemaking abstracts included below relate only to those prospective rulemakings that are likely to have a significant economic impact on a substantial number of small entities; the Regulatory Flexibility Act of 1980 requires publication of this information in the **Federal Register**. Also available elsewhere in this issue of the **Register** is the Department's submission to the Fiscal Year 2009 Regulatory Plan, as required under Executive Order 12866. The complete Regulatory Agenda of the Department is accessible online at www.reginfo.gov.

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

Dated: September 23, 2008.

Ann C. Agnew,

Executive Secretary to the Department.

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

Sequence Number	Title	Regulation Identifier Number
283	Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth	0930–AA10
284	Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addition **(Section 610 Review)**	0930–AA14

Centers for Disease Control and Prevention—Proposed Rule Stage

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

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
286	Control of Communicable Diseases Foreign Quarantine **(Reg Plan Seq No. 37)**	0920–AA12

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

Centers for Disease Control and Prevention—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
287	Control of Communicable Diseases, Interstate Quarantine, Passenger Information	0920–AA27

HHS

Centers for Disease Control and Prevention—Completed Actions

Sequence Number	Title	Regulation Identifier Number
288	Possession, Use, and Transfer of Select Agents and Toxins **(Section 610 Review)**	0920–AA29

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
289	Food Labeling; Serving Sizes and Nutrition Labeling **(Section 610 Review)**	0910–AF99
290	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures **(Section 610 Review)**	0910–AG14

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
291	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics	0910–AC52
292	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
293	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
294	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
295	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44
296	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
297	Over-the-Counter (OTC) Drug Review—Stimulant Drug Products	0910–AF56
298	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61
299	Over-the-Counter (OTC) Drug Review—Poison Treatment Drug Products	0910–AF68
300	Over-the-Counter (OTC) Drug Review—Urinary Analgesic Drug Products	0910–AF70
301	Process Controls for Animal Feed Ingredients and Mixed Animal Feed	0910–AG10
302	Pediatric Dosing for Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph	0910–AG12

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
303	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
304	Prevention of Salmonella Enteritidis in Shell Eggs **(Reg Plan Seq No. 40)**	0910–AC14
305	Requirements for Submission of In Vivo Bioequivalence Data	0910–AC23
306	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
307	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
308	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910–AF11
309	Cochineal Extract and Carmine Label Declaration	0910–AF12
310	Obstetrical and Gynecological Devices; Designation of Special Controls for Male Condoms Made of Natural Rubber Latex	0910–AF21
311	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
312	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
313	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
314	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
315	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
316	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
317	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
318	Substances Prohibited From Use in Animal Food or Feed To Prevent the Transmission of Bovine Spongiform Encephalopathy	0910–AF46
319	Over-the-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products	0910–AF51
320	Over-the-Counter (OTC) Drug Review—Antacid Products	0910–AF52

HHS

Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
321	Over-the-Counter (OTC) Drug Review—Skin Bleaching Products	0910–AF53
322	Over-the-Counter (OTC) Drug Review—Acne Drug Products Containing Benzoyl Peroxide	0910–AG00

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

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
323	Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements	0910–AB88
324	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
325	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40
326	Over-the-Counter Antidiarrheal Drug Products	0910–AF63
327	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
328	Status of Certain Additional Over-the-Counter Drug Category II Active Ingredients	0910–AF95
329	Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution **(Section 610 Review)**	0910–AG06

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
330	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910–AC35
331	Biological Products; Reporting of Biological Product Deviations in Manufacturing **(Section 610 Review)**	0910–AG05

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
332	Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P) **(Section 610 Review)**	0938–AP32
333	Changes to the Hospital Inpatient Prospective Payment System for FY 2010 (CMS-1406-P) **(Reg Plan Seq No. 42)**	0938–AP39
334	Revisions to Payment Policies under the Physician Fee Schedule for CY 2010 (CMS-1413-P) **(Reg Plan Seq No. 43)**	0938–AP40
335	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2010 (CMS-1414-P) **(Reg Plan Seq No. 44)**	0938–AP41

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

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
336	Updates to Electronic Transactions (Version 5010) (CMS-0009-F) **(Section 610 Review)**	0938–AM50
337	Revisions to HIPAA Code Sets (CMS-0013-F) **(Section 610 Review)**	0938–AN25
338	Home and Community-Based Services (HCBS) State Plan Option (CMS-2249-F) **(Section 610 Review)**	0938–AO53
339	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2009 (CMS-1404-F)	0938–AP17
340	Home Health Prospective Payment System Refinements and Rate Update for CY 2009 (CMS-1555-N)	0938–AP20

HHS

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
341	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P) **(Section 610 Review)**	0938–AG81
342	Electronic Claims Attachments Standards (CMS-0050-IFC)	0938–AK62
343	Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-6006-F) **(Section 610 Review)**	0938–AO84
344	Revisions to Payment Policies Under the Physician Fee Schedule for CY 2009 (CMS-1403-FC)	0938–AP18
345	Changes to Long Term Care Prospective Payment System Based on Specific Provisions in the Medicare, Medicaid, and SCHIP Extension Act of 2007 (CMS-1493-F)	0938–AP33

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
346	Medicare and Medicaid Programs; Hospice Care Conditions of Participation (CMS-3844-F) **(Completion of a Section 610 Review)**	0938–AH27
347	Inpatient Psychiatric Facility Prospective Payment System—Update for Rate Year Beginning July 1, 2008 (RY 2009) (CMS-1401-N)	0938–AO92
348	Prospective Payment System for Long-Term Care Hospitals RY 2009: Annual Payment Rate Updates (CMS-1393-F)	0938–AO94
349	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2009 (CMS-1534-F)	0938–AP11
350	Hospice Wage Index for FY 2009 (CMS-1548-F)	0938–AP14

Department of Health and Human Services (HHS) — Long-Term Actions

Substance Abuse and Mental Health Services Administration (SAMHSA)

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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

RIN: 0930–AA10

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: No

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

RIN: 0930–AA14

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

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

Legal Authority: Not Yet Determined

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

Timetable:

Action	Date	FR Cite
NPRM	02/00/09	

Regulatory Flexibility Analysis Required: Yes

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

RIN: 0920–AA23

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

286. CONTROL OF COMMUNICABLE DISEASES FOREIGN QUARANTINE

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

RIN: 0920–AA12

Department of Health and Human Services (HHS) — Long-Term Actions
Centers for Disease Control and Prevention (CDC)

287. ● CONTROL OF COMMUNICABLE DISEASES, INTERSTATE QUARANTINE, PASSENGER INFORMATION

Legal Authority: Not Yet Determined

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. The CDC Director has been delegated the responsibility for carrying out these regulations. The Director's authority to investigate suspected cases and potential spread of communicable disease among interstate travelers is thus not limited to those known or suspected of having a quarantinable disease, but rather all communicable diseases that may necessitate a public health response.

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

Because CDC has separated this provision from the rest of 42 CFR 70, CDC is requesting a separate entry in the Unified Agenda and a new RIN for this regulation.

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

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

RIN: 0920–AA27

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

Completed Actions

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

Legal Authority: PL 107–188

Abstract: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the HHS Secretary to regulate the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. These regulations are set forth at 42 CFR 73. Criteria used to determine whether a select agent or toxin should be included under the provisions of these regulations are based on: 1) The effect on human health as a result of exposure to the agent or toxin; 2) the degree of contagiousness of the agent or toxin; 3) the methods by which the agent or toxin is transferred to humans; 4) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and 5) any other criteria, including the needs of children and other vulnerable populations that the HHS Secretary considers appropriate. Based on these criteria, we are proposing to amend the list of HHS select agents and toxins by adding Chapare virus to the list.

Timetable:

Action	Date	FR Cite
Final Action	10/16/08	73 FR 61363
Final Action Effective	11/17/08	

Regulatory Flexibility Analysis Required: No

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

RIN: 0920–AA29

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

Prerule Stage

289. FOOD LABELING; SERVING SIZES AND NUTRITION LABELING (SECTION 610 REVIEW)

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

Abstract: Section 101.9 (21 CFR part 101.9) describes the nutrition labeling requirements for foods. Section 101.12 (21 CFR part 101.2) specifies the reference amount customarily consumed per eating occasion for each food category. The reference amount customarily consumed of a food is the basis for the serving size that is declared in the food's nutrition labeling. Under section 101.9, the serving size must be expressed in a common household measure that is appropriate to the food. The most recent change to sections 101.9 and 101.12 was in 1999, when FDA amended these regulations to reduce the reference amount customarily consumed for baking powder, baking soda, and pectin, and to include 1/8 teaspoon as an allowable unit of household measure for nutrition labeling purposes. FDA is undertaking a review of sections 101.9 and 101.12 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in sections 101.9 and 101.12 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for the regulations in sections 101.9 and 101.12; (2) the nature of complaints or comments received concerning the regulations in sections 101.9 and 101.12; (3) the complexity of the regulations; (4) the extent to which the regulations in sections 101.9 and 101.12 overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in sections 101.9 and 101.12.

Timetable:

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

Regulatory Flexibility Analysis Required: Undetermined

Agency Contact: Mary Brandt, Statistician, Department of Health and Human Services, Food and Drug Administration, Center for Food Safey and Applied Nutrition, 5100 Paint Branch Parkway, ONLDS (HFS–820), College Park, MD 20740
Phone: 301 436–1788
Fax: 301 436–1191
Email: mary.brandt@fda.hhs.gov

RIN: 0910–AF99

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

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

Abstract: FDA is undertaking a review of 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (2) the nature of complaints or comments received from the public concerning the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (3) the complexity of the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763);

HHS—FDA **Prerule Stage**

(4) the extent to which the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State and local governmental rules, and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763).

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Bldg. 51, Room 6234, Silver Spring, MD 20993–0002
Phone: 301 796–3601
Fax: 301 847–8440
Email: howard.mullerjr@fda.hhs.gov

RIN: 0910–AG14

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

Proposed Rule Stage

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	09/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Martha Nguyen, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Bldg. 51, Room 6224, Silver Spring, MD 20993–0002
Phone: 301 796–3471
Fax: 301 847–8440
Email: martha.nguyen@fda.hhs.gov

RIN: 0910–AC52

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

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

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796–0885
Fax: 301 796–9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910–AF31

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

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

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action will address laxative drug products. The second action will address the professional labeling for sodium phosphate drug products. The third action will address all other professional labeling requirements for laxative drug products.

Timetable:

Action	Date	FR Cite
Final Action (Granular Psyllium)	03/29/07	72 FR 14669
Final Action (Laxative Drug Products)	To Be	Determined
NPRM (Professional Labeling – Sodium Phosphate)	05/00/09	
NPRM (Professional Labeling)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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

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RIN: 0910–AF38

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

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

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

Timetable:

Action	Date	FR Cite
ANPRM (Sunscreen and Insect Repellent)	02/22/07	72 FR 7941
ANPRM Comment Period End	05/23/07	
NPRM (UVA/UVB)	08/27/07	72 FR 49070
NPRM Comment Period End	12/26/07	
NPRM (Time and Extent)	05/00/09	
Final Action (UVA/UVB)	06/00/09	
NPRM (Sunscreen and Insect Repellent)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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Email: walter.ellenberg@fda.hhs.gov

RIN: 0910–AF43

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

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

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AF44

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

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

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF45

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

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

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Hangover)	09/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF56

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	09/18/08	73 FR 54106
NPRM Comment Period End	12/02/08	
Final Rule	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF61

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

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

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

Timetable:

Action	Date	FR Cite
NPRM (IPECAC)	09/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AF68

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

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

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

Timetable:

Action	Date	FR Cite
NPRM (Urinary Analgesic)	09/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AF70

301. PROCESS CONTROLS FOR ANIMAL FEED INGREDIENTS AND MIXED ANIMAL FEED

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

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

Timetable:

Action	Date	FR Cite
NPRM	05/00/09	

Regulatory Flexibility Analysis Required: Yes

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

HHS—FDA

Proposed Rule Stage

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

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

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a monograph is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will propose changes to the final monograph to address safety and efficacy issues associated with pediatric cough and cold products.

Timetable:

Action	Date	FR Cite
NPRM	09/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG12

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

Final Rule Stage

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	03/14/03	68 FR 12406
NPRM Comment Period Extended	06/18/03	
NPRM Comment Period End	07/14/03	
NPRM Comment Period Extension End	10/14/03	
Final Action	07/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Bldg. 51, Room 6306, Silver Spring, MD 20993–0002
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RIN: 0910–AA97

304. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

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

RIN: 0910–AC14

305. REQUIREMENTS FOR SUBMISSION OF IN VIVO BIOEQUIVALENCE DATA

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

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

Timetable:

Action	Date	FR Cite
NPRM	10/29/03	68 FR 61640
Final Action	12/00/08	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AC23

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

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

Abstract: The Food and Drug Administration is amending its current good manufacturing practice regulations and other regulations to clarify and strengthen requirements for the label, color, dedication, and design of medical gas containers and closures. Despite existing regulatory

requirements and industry standards for medical gases, there have been repeated incidents in which cryogenic containers of harmful industrial gases have been connected to medical oxygen supply systems in hospitals and nursing homes, and subsequently administered to patients. These incidents have resulted in death and serious injury. There have also been several incidents involving high-pressure medical gas cylinders that have resulted in death and injuries to patients. These amendments, together with existing regulations, are intended to ensure that the types of incidents that have occurred in the past, as well as other types of foreseeable and potentially deadly medical gas mixups, do not occur in the future.

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AC53

307. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES

Legal Authority: PL 105–115, sec 121

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

Timetable:

Action	Date	FR Cite
NPRM	09/20/05	70 FR 55038
NPRM Comment Period End	12/19/05	
Final Action	03/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AC55

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	05/29/08	73 FR 30831
NPRM Comment Period End	08/27/08	
Final Action	09/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF11

309. COCHINEAL EXTRACT AND CARMINE LABEL DECLARATION

Legal Authority: 21 USC 379e(b)

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

Timetable:

Action	Date	FR Cite
NPRM	01/30/06	71 FR 4839
NPRM Comment Period End	05/01/06	
Final Action	11/00/08	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF12

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

Legal Authority: 21 USC 360c

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

effectiveness of condoms in preventing sexually transmitted diseases is medically accurate.

Timetable:

Action	Date	FR Cite
NPRM	11/14/05	70 FR 69102
NPRM Comment Period End	02/13/06	
Final Action	12/00/08	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF21

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

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

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment – Ephedrine Single Ingredient)	07/13/05	70 FR 40237
Final Action (Technical Amendment)	11/30/07	72 FR 63679
Final Action (Amendment – Ephedrine Single Ingredient)	04/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF32

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

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

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF33

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

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

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Sinusitis Claim)	08/02/04	69 FR 46119
NPRM (Phenylephrine Bitartrate)	11/02/04	69 FR 63482
NPRM (Phenylpropanol amine)	12/22/05	70 FR 75988
Final Action (Amendment) (Sinusitis Claim)	10/31/05	70 FR 58974
Final Action (Phenylephrine Bitartrate)	08/01/06	71 FR 83358
Final Action (Phenylpropanol amine)	09/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF34

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

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

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The final action addresses the 2003 proposed rule on patches, plasters, and poultices. The proposed rule will address issues not addressed in previous rulemakings.

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF35

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

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

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Required Warnings and Other Labeling)	12/26/06	71 FR 77314
NPRM Comment Period End	05/25/07	
NPRM (Amendment) (Overindulgence/ Hangover)	09/00/09	
NPRM (Amendment) (Pediatric)	To Be	Determined
NPRM (Amendment) (Combinations with Sodium Bicarbonate)	09/00/09	
NPRM (Amendment) (Miscellaneous Issues)	09/00/09	
Final Action (Required Warnings and Other Labeling)	03/00/09	
Final Action (Internal Analgesics)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF36

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

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

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

Timetable:

Action	Date	FR Cite
NPRM (Convenience Sizes)	12/12/06	71 FR 74474
Final Action	09/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF37

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

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

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF42

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

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

Abstract: On October 6, 2005, the Food and Drug Administration (FDA) proposed to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals to help strengthen existing safeguards to prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. The discovery of a BSE-positive dairy cow in December 2003 has caused FDA to review its policies for prevention of BSE, which resulted in this rulemaking. FDA is correcting the final rule on BSE that appeared in the Federal Register of April 25, 2008 (73 FR 22719-22758). The final rule inadvertently published with incorrect dollar amounts in two separate areas: the summary of economic impacts and the paperwork burden table.

Timetable:

Action	Date	FR Cite
ANPRM	07/14/04	69 FR 42288
ANPRM Comment Period End	08/13/04	
NPRM	10/06/05	70 FR 58569
NPRM Comment Period End	12/20/05	
Final Rule	04/25/08	73 FR 22720
Final Rule–Correction	11/00/08	
Final Rule Effective	04/27/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF46

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

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

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	01/05/05	70 FR 741
Final Action	09/00/09	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF51

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

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

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

Timetable:

Action	Date	FR Cite
Final Action (Sodium Bicarbonate Labeling)	09/00/09	
Final Action (Overindulgence Labeling)	09/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AF52

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	08/29/06	71 FR 51146
NPRM Comment Period End	12/27/06	
Final Action	09/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AF53

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

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

HHS—FDA **Final Rule Stage**

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

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

Timetable:

Action	Date	FR Cite
Final Action	05/00/09	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AG00

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

Long-Term Actions

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

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

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

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AB88

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

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

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Emergency First Aid Eyewashes)	02/19/03	68 FR 7917
NPRM (Amendment) (Emergency First Aid Eyelashes)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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

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

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

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new

drug application, may be legally marketed. This action will address oral health care products used to reduce or prevent dental plaque and gingivitis.

Timetable:

Action	Date	FR Cite
ANPRM (Plaque Gingivitis)	05/29/03	68 FR 32232
ANPRM Comment Period End	08/27/03	
NPRM (Plaque Gingivitis)	To Be	Determined
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AF40

326. OVER–THE–COUNTER ANTIDIARRHEAL DRUG PRODUCTS

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

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

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AF63

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

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

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

Timetable:

Action	Date	FR Cite
NPRM (Food Handlers)	To Be	Determined
NPRM (Testing)	To Be	Determined
NPRM (Consumer)	To Be	Determined
Final Action (Healthcare)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AF69

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	06/19/08	73 FR 34895
NPRM Comment Period End	09/17/08	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD–560, 5600 Fishers Lane, Rockville, MD 20857
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RIN: 0910–AF95

329. FOOD LABELING: SAFE HANDLING STATEMENTS, LABELING OF SHELL EGGS; REFRIGERATION OF SHELL EGGS HELD FOR RETAIL DISTRIBUTION (SECTION 610 REVIEW)

Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 331; 21 USC 342 and 343; 21 USC 348; 21 USC 371; 42 USC 243; 42 USC 264; 42 USC 271

Abstract: Section 101.17 (h) (21 CFR 101.17(h)) describes requirements for the labeling of the cartons of shell eggs that have not been treated to destroy Salmonella microorganisms. Section 115. 50 (21 CFR 115.50) describes requirements for refrigeration of shell eggs held for retail distribution. Section 16.5(a)(4) provides that part 16 does not apply to a hearing on an order for relabeling, diversion, or destruction if shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and sections 101.17(h) and 115.50. FDA amended 21 CFR 101.17(h) on August 20, 2007 (72 FR 46375) to permit the safe handling statement to appear on the inside lid of egg cartons to provide the industry greater flexibility in the placement of the statement. FDA is undertaking a review of 21 CFR sections 101.17(h), 115.50,

and 16.5(a)(4) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in sections 101.17(h), 115.50 and 16.5(a)(4) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

Timetable:

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

Regulatory Flexibility Analysis Required: Undetermined

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

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

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

Legal Authority: 21 USC 355b

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

Completed:

Reason	Date	FR Cite
Final Action	10/28/08	73 FR 63886

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Carol Drew
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RIN: 0910–AC35

331. BIOLOGICAL PRODUCTS; REPORTING OF BIOLOGICAL PRODUCT DEVIATIONS IN MANUFACTURING (SECTION 610 REVIEW)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262 and 263; 42 USC 263a; 42 USC 264; 42 USC 300aa–25

Abstract: Section 600.14 (21 CFR 600.14) requires licensed manufacturers of biological products to report to FDA biological product deviations in manufacturing. Section 606.170 requires licensed manufacturers of blood and blood components including Source Plasma, unlicensed registered establishments, and transfusion services to report to FDA biological product deviations in manufacturing. Under section 610 of the Regulatory Flexibility Act, FDA has undertaken a review of these regulations in parts 600 and 606 under section 610. The purpose of this review was to determine whether the regulations in parts 600 and 606 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA solicited comments on the following: 1) The continued need for the regulations; 2) the nature of complaints or comments received concerning the regulations; 3) the complexity of the regulations; 4) the extent to which a regulation in parts 600 or 606 overlaps, duplicates, or conflicts with other Federal rules, and to the extent feasible, with State and local government rules; and 5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations.

FDA did not receive any comments during the review process of these regulations under section 610 review, therefore these regulations will continue without change.

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

Completed:

Reason	Date	FR Cite
Begin Review	05/05/08	
End Review	11/03/08	

Regulatory Flexibility Analysis Required: No

Agency Contact: Stephen M. Ripley
Phone: 301 827–6210

RIN: 0910–AG05

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

Proposed Rule Stage

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

Legal Authority: 42 USC 1302; 42 USC 1395hh

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

Timetable:

Action	Date	FR Cite
NPRM	12/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Trish Brooks, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AP32

333. ● CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM FOR FY 2010 (CMS–1406–P)

Regulatory Plan: This entry is Seq. No. 42 in part II of this issue of the **Federal Register**.

RIN: 0938–AP39

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

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

RIN: 0938–AP40

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

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

RIN: 0938–AP41

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

Final Rule Stage

336. UPDATES TO ELECTRONIC TRANSACTIONS (VERSION 5010) (CMS–0009–F) (SECTION 610 REVIEW)

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

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

Timetable:

Action	Date	FR Cite
NPRM	08/22/08	73 FR 49741
NPRM Comment Period End	10/21/08	
Final Action	11/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Gladys C. Wheeler, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of E–Health Standards and Services, Mailstop S2–24–18, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AM50

337. REVISIONS TO HIPAA CODE SETS (CMS–0013–F) (SECTION 610 REVIEW)

Legal Authority: PL 104–191

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

Timetable:

Action	Date	FR Cite
NPRM	08/22/08	73 FR 49795
NPRM Comment Period End	10/21/08	
Final Action	11/00/08	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AN25

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	04/04/08	73 FR 18676
NPRM Comment Period End	06/03/08	
Final Action	11/00/08	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AO53

HHS—CMS **Final Rule Stage**

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	07/18/08	73 FR 41416
NPRM Comment Period End	09/02/08	
Final Action	11/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Alberta Dwivedi, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–01–26, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AP17

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

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

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

Timetable:

Action	Date	FR Cite
Notice	11/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Randy Throndset, Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–07–28, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AP20

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

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End	06/09/97	
Second NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Undetermined

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

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

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

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Elizabeth Holland, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of E–Health Standards and Services, Mailstop S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AK62

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

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

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

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Frank Whelan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Mailstop C3–02–16, 7500 Security Boulevard, Baltimore, MD 21244
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RIN: 0938–AO84

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	07/07/08	73 FR 38502
NPRM Comment Period End	08/29/08	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP18

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

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

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

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/06/08	73 FR 24871
Interim Final Rule	05/22/08	73 FR 29699
Final Action	05/00/11	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP33

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

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

Legal Authority: 42 USC 1302; 42 USC 1395hh

Abstract: This final rule is a regulatory reform initiative that revises existing conditions of participation that hospices must meet to participate in the Medicare and Medicaid programs. The requirements focus on the actual care delivered to patients and patients' families by hospices and the results of that care, reflect an interdisciplinary view of patient care, and allow hospices greater flexibility in meeting quality standards. These changes are an integral part of our efforts to achieve broad-based improvements and measurements of the quality of care furnished through Federal programs while at the same time reducing procedural burdens on providers.

Timetable:

Action	Date	FR Cite
NPRM	05/27/05	70 FR 30840
Final Action	06/05/08	73 FR 32087

Regulatory Flexibility Analysis Required: No

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RIN: 0938–AH27

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

Legal Authority: PL 106–113, sec 124 BBRA

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

Completed:

Reason	Date	FR Cite
Notice	05/07/08	73 FR 25709

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AO92

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

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

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

Completed:

Reason	Date	FR Cite
Final Action	05/09/08	73 FR 26788

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AO94

349. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2009 (CMS–1534–F)

Legal Authority: Social Security Act, sec 1886(e)

Abstract: This major rule updates the payment rates used under the Skilled Nursing Facilities Prospective Payment System beginning October 1, 2008.

Completed:

Reason	Date	FR Cite
NPRM	05/07/08	73 FR 25918
Final Action	08/08/08	73 FR 46415

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP11

350. HOSPICE WAGE INDEX FOR FY 2009 (CMS–1548–F)

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

Abstract: This rule updates the annual hospice wage index for FY 2009. The wage index is used to reflect local differences in wage levels.

Completed:

Reason	Date	FR Cite
NPRM	05/01/08	73 FR 24000
Final Action	08/08/08	73 FR 46463

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP14

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