HHS

Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identifier Number
824	Tax Refund Offset	0991–AB17
825	Implementation of the Equal Access to Justice Act in Agency Proceedings	0991–AB22
826	OIG Civil Money Penalties Under the Medicare Prescription Drug Discount Card Program	0991–AB30

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

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

Substance Abuse and Mental Health Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
828	Mandatory Guidelines for the Federal Workplace Drug Testing Program	0930–AA12

Substance Abuse and Mental Health Services Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
829	Substance Abuse and Mental Health Services Administration (SAMHSA) Charitable Choice	0930–AA11
830	Mandatory Guidelines for Federal Workplace Drug Testing Programs; Specimen Validity Testing	0930–AA13

Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
831	Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices	0920–AA04

Centers for Disease Control and Prevention—Completed Actions

Sequence Number	Title	Regulation Identifier Number
832	Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employee Occupational Illness Compensation Act of 2000	0920–AA07

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
833	Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
834	Food Labeling; Prominence of Calories	0910–AF22
835	Food Labeling; Serving Sizes	0910–AF23
836	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43

HHS

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
837	Foreign and Domestic Establishment Registration and Listing Requirements for Drugs and Biologics	0910–AA49
838	Applications for FDA Approval To Market a New Drug; Complete Response Letter; Amendments To Unapproved Applications	0910–AB34
839	Prevention of Salmonella Enteritidis in Shell Eggs	0910–AC14
840	Exception From General Requirements for Informed Consent; Request for Comments and Information	0910–AC25
841	Medical Devices; Anesthesiology Devices; Proposed Reclassification of Pressure Regulators for Use With Medical Oxygen	0910–AC30
842	Food Standards: General Principles and Food Standards Modernization	0910–AC54
843	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
844	Reporting Information Regarding Falsification of Data	0910–AC59
845	Definition of "Serious Adverse Health Consequences" Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AF06
846	Health Claims	0910–AF09
847	Quality Standard Regulation Establishing Allowable Level for Arsenic in Bottled Water	0910–AF10
848	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation	0910–AF11
849	Cochineal Extract and Carmine Label Declaration	0910–AF12
850	Charging for Investigational Drugs	0910–AF13
851	Treatment Use of Investigational Drugs	0910–AF14
852	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Derivatives of Blood	0910–AF16
853	Use of Ozone-Depleting Substances: Removal of Essential Use Designation; Albuterol	0910–AF18
854	Revocation of the Status of Specific Products; Group A Streptococcus	0910–AF20
855	Latex Condoms: Special Controls	0910–AF21
856	Blood Initiative—Regulations for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use	0910–AF25
857	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
858	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
859	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
860	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
861	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
862	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
863	Investigational New Drugs: Export Requirements for Unapproved New Drug Products	0910–AA61
864	Labeling for Human Prescription Drugs; Revised Format	0910–AA94
865	Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement	0910–AB28
866	CGMP for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection (Lookback)	0910–AB76
867	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements	0910–AB88
868	Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products	0910–AC07
869	Medical Devices; Patient Examination and Surgeons' Gloves; Adulteration	0910–AC32
870	Amendments to the Performance Standard for Diagnostic X-Ray Systems and Their Major Components	0910–AC34
871	Establishment and Maintenance of Records Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC39
872	Registration of Food and Animal Feed Facilities	0910–AC40
873	Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC41
874	Presubmission Conferences	0910–AC44
875	Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application	0910–AF15
876	Blood Initiative—Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma	0910–AF26

HHS

Food and Drug Administration—Final Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
877	Over-the-Counter (OTC) Drug Review—Antiperspirant Products	0910–AF30
878	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
879	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
880	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
881	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
882	Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food	0910–AB96
883	Chronic Wasting Disease: Control of Food Products and Cosmetics Derived From Exposed Animal Populations	0910–AC21
884	Requirements for Submission of In Vivo Bioequivalence Data	0910–AC23
885	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910–AC35
886	Food Labeling: Trans Fatty Acids in Nutrition Labeling: Consumer Research To Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements	0910–AC50
887	Submission of Standardized Electronic Study Data From Clinical Studies Evaluating Human Drugs and Biologics	0910–AC52
888	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
889	Food Labeling: Food Allergen Ingredient Labeling	0910–AF07
890	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls	0910–AF08
891	Current Good Manufacutring Practices; Quality Control Procedures; Notification Requirements; Records and Reports	0910–AF27
892	Infant Formula Quality Factors	0910–AF28
893	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
894	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
895	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
896	Over-the-Counter (OTC) Drug Review	0910–AA01
897	Infant Formula: Requirements Pertaining to Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports	0910–AA04
898	Determination That Informed Consent Is Infeasible or Is Contrary to the Best Interest of Recipients	0910–AA89
899	Blood Initiative	0910–AB26
900	Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products	0910–AB27
901	Supplements and Other Changes to an Approved Application	0910–AB61
902	Current Good Manufacturing Practice for Medicated Feeds	0910–AB70
903	Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format	0910–AB91
904	Use of Materials Derived From Bovine and Ovine Animals in FDA-Regulated Products	0910–AC19
905	Bar Code Label Requirements for Human Drug Products and Blood	0910–AC26
906	Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–AC38
907	Requirements for Liquid Medicated Feed and Free-Choice Medicated Feed	0910–AC43
908	Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review	0910–AC56
909	Revision of the Requirements for Spore-Forming Microorganisms	0910–AC57
910	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (Part 110) **(Completion of a Section 610 Review)**	0910–AC58
911	Over-the-Counter (OTC) Drug Review—Antidiarrheal Products	0910–AF29

HHS—FDA

Prerule Stage

Federalism: Undetermined

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RIN: 0910-AF23

836. • OVER-THE-COUNTER (OTC) DRUG REVIEW—SUNSCREEN PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
ANPRM (Sunscreen and Insect Repellent)	11/00/04	
NPRM (UVA/UVB)	11/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD-560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
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Related RIN: Split from 0910-AA01

RIN: 0910-AF43

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

Proposed Rule Stage

837. FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING REQUIREMENTS FOR DRUGS AND BIOLOGICS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 262; 42 USC 264; 42 USC 271

CFR Citation: 21 CFR 20; 21 CFR 201; 21 CFR 207; 21 CFR 314; 21 CFR 330; 21 CFR 514; 21 CFR 515; 21 CFR 601; 21 CFR 607; 21 CFR 610; 21 CFR 1271

Legal Deadline: None

Abstract: The proposed rule would amend FDA regulations on the registration of producers of drugs and the listing of drugs in commercial distribution. The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list drugs or biologics regulated as drugs. The proposal describes when, how, and where to register and list, and what information must be submitted for registration and listing. The proposed regulations would also revise the requirements for the National Drug Code number and would require the electronic submission of most registration and listing information.

Timetable:

Action	Date	FR Cite
NPRM	11/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD-7), Rockville, MD 20852
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RIN: 0910-AA49

838. APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG; COMPLETE RESPONSE LETTER; AMENDMENTS TO UNAPPROVED APPLICATIONS

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 312; 21 CFR 314

Legal Deadline: None

Abstract: The proposed rule would amend the regulations on marketing approval of new drugs to discontinue the use of approvable and not approvable letters when taking action on a marketing application and instead use complete response letters. The proposed rule would also amend the regulations on extension of the review clock because of amendments to applications.

Timetable:

Action	Date	FR Cite
NPRM	07/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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RIN: 0910-AB34

Standard of Potency." The vaccines had been licensed by the National Institutes of Health prior to 1972, when regulatory authority over these vaccines was transferred to FDA. The regulation prohibits the use of Group A streptococcus organisms and derivatives of Group Astreptococcus as ingredients in Bacterial Vaccines and Bacterial Antigens with "No U.S. Standard of Potency." The regulation was never intended to refer to purified streptococcus vaccines, which were not developed at that time. Therefore, the regulation is being revoked.

Timetable:

Action	Date	FR Cite
NPRM – Companion to Direct Final Rule	04/00/05	
Direct Final Rule	04/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Valerie Butler, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM-17), HFM-17, 1401 Rockville Pike, Rockville, MD 20852
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RIN: 0910-AF20

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855. • LATEX CONDOMS: SPECIAL CONTROLS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

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

CFR Citation: 21 CFR 884.5300; 21 CFR 884.5310

Legal Deadline: None

Abstract: The classification regulations for male condoms would be amended to specify a labeling guidance document as a special control for condoms made from NR latex. The new special control guidance document would provide detailed recommendations for labeling meeting the requirements of 21 CFR 801, that together with the general controls, provides a resaonable assurance of the safety and effectiveness of these devices. The rule will demonstrate how the agency is moving forward to meet the congressionaldirective of Public Law 106-554 that FDA review condom labeling to assure that the information regarding sexually transmitted disease transmission is medically accurate.

Timetable:

Action	Date	FR Cite
NPRM	12/00/04	

Regulatory Flexibility Analysis Required: Undetermined

Small Entities Affected: Businesses

Government Levels Affected: None

Federalism: Undetermined

Agency Contact: Joseph M. Sheehan, Chief, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, HFZ-215, Center for Devices and Radiological Health, HFZ-215, 1350 Piccard Drive, Rockville, MD 20850
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RIN: 0910-AF21

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856. • BLOOD INITIATIVE—REGULATIONS FOR HUMAN BLOOD AND BLOOD COMPONENTS INTENDED FOR TRANSFUSION OR FOR FURTHER MANUFACTURING USE

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

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

CFR Citation: 21 CFR 600; 21 CFR 601; 21 CFR 606; 21 CFR 607; 21 CFR 610; ...

Legal Deadline: None

Abstract: In multiple rulemakings, the Food and Drug Administration (FDA) is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, Source Plasma, and blood-derivative products to be more consistent with current practices and to remove unnecessary or outdated requirements. This action is based on FDA's comprehensive review of the biologics regulations. It is also based on reports by the U.S. House of Representatives Committee on Government Reform and Oversight Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute of Medicine, as well as on public comments. The other remaining subject intended to be addressed in the rulemakings include: labeling of blood and blood components (0910-AF26). These actions are intended to help ensure the continued safety of the Nation's blood supply.

Timetable:

Action	Date	FR Cite
NPRM	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Paula S. McKeever, Regulatory Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Suite 200N (HFM-17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448
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Related RIN: Split from 0910-AB26

RIN: 0910-AF25

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857. • OVER-THE-COUNTER (OTC) DRUG REVIEW—COUGH/COLD (BRONCHODILATOR) PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of

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Related RIN: Split from 0910-AA01

RIN: 0910-AF32

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858. • OVER-THE-COUNTER (OTC) DRUG REVIEW—COUGH/COLD (COMBINATION) PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Split from 0910-AA01

RIN: 0910-AF33

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859. • OVER-THE-COUNTER (OTC) DRUG REVIEW—COUGH/COLD (NASAL DECONGESTANT) PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM (Phenylephrine Bitartrate)	09/00/04	
NPRM (Phenyl-propanolamine)	09/00/04	
NPRM (Amendment) (Sinusitis Claim)	10/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Split from 0910-AA01

RIN: 0910-AF34

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860. • OVER-THE-COUNTER (OTC) DRUG REVIEW—INTERNAL ANALGESIC PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Labeling)	08/00/04	
NPRM (Amendment) (Pediatric)	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Split from 0910-AA01

RIN: 0910-AF36

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861. • OVER-THE-COUNTER (OTC) DRUG REVIEW—LABELING OF DRUG PRODUCTS FOR OTC HUMAN USE

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

HHS—FDA

Proposed Rule Stage

Timetable:

Action	Date	FR Cite
NPRM (Convenience Sizes)	08/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Split from 0910-AA01

RIN: 0910-AF37

862. • OVER-THE-COUNTER (OTC) DRUG REVIEW—WEIGHT CONTROL PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
NPRM (Phenyl-propanolamine)	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

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Related RIN: Split from 0910-AA01

RIN: 0910-AF45

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

Final Rule Stage

863. INVESTIGATIONAL NEW DRUGS: EXPORT REQUIREMENTS FOR UNAPPROVED NEW DRUG PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321; 21 USC 381; 21 USC 382; 21 USC 393; 42 USC 241; 42 USC 243; 42 USC 262; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371

CFR Citation: 21 CFR 312.110

Legal Deadline: None

Abstract: The final rule would amend the regulations on the exportation of unapproved new drug products, including biological products, for investigational use. In general, the rule would provide four different routes for exporting an unapproved new drug product for investigational use. One route would permit exportation, if the drug is the subject of an investigational new drug application (IND) and is being exported for use in the investigation. A second route would permit exportation, without prior Food and Drug Administration (FDA) approval and without an IND, if the product is to be exported for use in a clinical investigation and has received marketing authorization in certain developed countries. The third route would permit exportation, without prior FDA approval and without an IND, if the product is to be exported for use in a clinical investigation in certain specified developed countries. The fourth route would permit exportation without an IND, to any country provided that the exporter sends a written certification to FDA at the time the drug is first exported. Drugs exported under any of the first three routes would, however, be subject to certain statutory requirements, such as not conflicting with the foreign country's laws and not being sold or offered for sale in the United States. Drugs exported under either the second or third routes would be subject to additional statutory requirements, such as being in substantial conformity with the current good manufacturing practices and certain labeling requirements. These provisions would implement changes in FDA's export authority resulting from the FDA Export Reform and Enhancement Act of 1996.

Timetable:

Action	Date	FR Cite
NPRM	06/19/02	67 FR 41642
Final Action	09/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

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RIN: 0910-AA61

864. LABELING FOR HUMAN PRESCRIPTION DRUGS; REVISED FORMAT

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

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

CFR Citation: 21 CFR 201

Legal Deadline: None

Abstract: This regulation is one component of the Secretary's initiative to reduce medical errors. The regulation would amend the regulations governing the format and content of professional labeling for human

and Human Services, Food and Drug Administration, HFV-100, Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855
Phone: 301 827-0205

Related RIN: Previously reported as 0910-AB68

RIN: 0910-AC44

875. HUMAN SUBJECT PROTECTION; FOREIGN CLINICAL STUDIES NOT CONDUCTED UNDER AN INVESTIGATIONAL NEW DRUG APPLICATION

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

Legal Authority: 21 USC 355(d)(5); 21 USC 355(i); 21 USC 371(a); 42 USC 262(a)(2)(A); 42 USC 262(a)(2)(B)(i)(I)

CFR Citation: 21 CFR 312.120

Legal Deadline: None

Abstract: The proposed rule would update the standards for the acceptance of foreign clinical studies not conducted under an investigational new drug application (IND) as support for an IND or marketing application for a drug or biological product. We are proposing to replace the requirement in 21 CFR 312.120 that non-IND foreign clinical studies be conducted in accordance with ethical principles stated in the Declaration of Helsinki. We would replace that with a requirement that such studies be conducted in accordance with good clinical practice (GCP), including review and approval by an independent ethics committee. The proposed GCP standard is consistent with the standard of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for GCP and is sufficiently flexible to accommodate differences in how countries regulate the conduct of clinical research and obtain the informed consent of patients.

Timetable:

Action	Date	FR Cite
NPRM	06/10/04	69 FR 32467
Final Action	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD-7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD-7), Rockville, MD 20852
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RIN: 0910-AF15

876. • BLOOD INITIATIVE—REVISIONS TO LABELING AND STORAGE REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS, INCLUDING SOURCE PLASMA

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

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

CFR Citation: 21 CFR 600; 21 CFR 601; 21 CFR 606; 21 CFR 607; 21 CFR 610; ...

Legal Deadline: None

Abstract: In multiple rulemakings, the Food and Drug Administration (FDA) is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood, blood components, Source Plasma, and blood-derivative products to be more consistent with current practices and to remove unnecessary or outdated requirements. This action is based on FDA's comprehensive review of the biologics regulations. It is also based on reports by the U.S. House of Representatives Committee on Government Reform and Oversight Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute of Medicine, as well as on public comments. The other remaining subject intended to be addressed in the rulemakings include: donor eligibility requirements (0910-AF25). These actions are intended to help ensure the continued safety of the Nation's blood supply.

Timetable:

Action	Date	FR Cite
Final Action	06/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Sharon Carayiannis, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Suite 400S (HFM-17), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448
Phone: 301 827-6210

Related RIN: Split from 0910-AB26

RIN: 0910-AF26

877. • OVER-THE-COUNTER (OTC) DRUG REVIEW—ANTIPERSPIRANT PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
Final Action (Partial Stay)	09/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD-560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 827-2241
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Email: rachanow@cder.fda.gov

Related RIN: Split from 0910-AA01

RIN: 0910-AF30

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

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
Final Action (Amendment) (Common Cold)	10/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF31

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

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
Final Action (Emergency First Aid Eyewashes)	11/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF39

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

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
Final Action (Technical Amendments)	12/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF42

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

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
Final Action (Warnings)	11/00/04	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
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Email: rachanow@cder.fda.gov

Related RIN: Split from 0910–AA01

RIN: 0910–AF44

Federalism: Undetermined

Agency Contact: Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Suite 3037 (HFD–7), Center for Drug Evaluation and Research, 5515 Security Lane, Suite 1101 (HFD–7), Rockville, MD 20852
Phone: 301 594–2041
Fax: 301 827–5562
Email: mullerh@cder.fda.gov

RIN: 0910–AF08

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891. CURRENT GOOD MANUFACUTRING PRACTICES; QUALITY CONTROL PROCEDURES; NOTIFICATION REQUIREMENTS; RECORDS AND REPORTS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371; ...

CFR Citation: 21 CFR 106; 21 CFR 107

Legal Deadline: None

Abstract: The agency published a proposed rule on July 9, 1996, that would establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and records and reports for the production of infant formula. This proposal was issued in response to the 1986 Amendments to the Infant Formula Act of 1980. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment period was extended on June 27, 2003, to end onAugust 26, 2003.

Timetable:

Action	Date	FR Cite
Final Action	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Melissa Scales, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–800, HFS–024, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1720
Email: melissa.scales@cfsan.fda.gov

Related RIN: Split from 0910–AA04

RIN: 0910–AF27

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892. INFANT FORMULA QUALITY FACTORS

Priority: Other Significant

Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371; ...

CFR Citation: 21 CFR 106; 21 CFR 107

Legal Deadline: None

Abstract: The agency published a proposed rule on July 9, 1996, that would establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and records and reports for the production of infant formula. This proposal was issued in response to the 1986 Amendments to the Infant Formula Act of 1980. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment period was extended on June 27, 2003, to end onAugust 26, 2003.

Timetable:

Action	Date	FR Cite
Final Action	09/00/05	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

Agency Contact: Melissa Scales, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, HFS–800, HFS–024, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740
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Related RIN: Split from 0910–AA04

RIN: 0910–AF28

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

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF35

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

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for

HHS—FDA **Long-Term Actions**

Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF38

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

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable: Next Action Undetermined

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over–the–Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD–560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
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Related RIN: Split from 0910–AA01

RIN: 0910–AF40

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

Completed Actions

896. OVER–THE–COUNTER (OTC) DRUG REVIEW

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21 USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

SMALL ENTITIES AFFECTED: The effects, if any, vary depending on the individual rulemaking. However, the Agency anticipates that the rules would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

Timetable:

Action	Date	FR Cite
Actions Will Continue Under Separate Rulemakings	06/08/04	
Anorectal Products (0910–AC65)		
Final Action (Amendment)	08/26/03	(68 FR 51167)
Antidiarrheal Products (0910–AC82)		
NPRM (Amendment) (Trav. Diar)	04/17/03	(68 FR 18915)
Merged With 0910-AF29	06/08/04	
Antiemetic Products (0910–AC71)		
Final Action (Amendment) (Warning)	12/06/02	(67 FR 72555)
Antiperspirant Products (0910–AC89)		
Final Action	06/09/03	(68 FR 34273)
Final Action (Partial Stay) Merged With 0910-AF30	06/08/04	
Cough/Cold (Antihistamine) Products (0910–AD31)		
Merged With 0910-AF31	06/08/04	
Cough/Cold (Antitussive) Products (0910–AD24)		
Final Action (Amendment) (Warning)	12/06/02	(67 FR 72555)
Cough/Cold (Bronchodilator) Products (0910–AD33)		
Merged With 0910-AF32	06/08/04	
Cough/Cold (Combination) Products (0910–AD25)		
Final Action	12/23/02	(67 FR 78158)
NPRM (Amendment) Merged With 0910-AF33	06/08/04	
Cough/Cold (Nasal Decongestant) Products (0910–AD43)		
Merged With 0910-AF34	06/08/04	
External Analgesic Products (0910–AD06)		
Final Action (Amendment)(Warning)	12/06/02	(67 FR 72555)
NPRM (Amendment)(Patches)	07/17/03	(68 FR 42324)
Merged With 0910-AF35	06/08/04	
Ingrown Toenail Relief Products (0910–AD21)		
NPRM	10/04/02	(67 FR 62218)
Final Action	05/07/03	(68 FR 24347)
Internal Analgesic Products (0910–AD07)		
NPRM (Amendment)(Ibuprofen)	08/21/02	(67 FR 54139)
Merged With 0910-AF36	06/08/04	
Labeling of Drug Products for OTC Human Use (0910–AD47)		
NPRM (Sodium Labeling)	03/24/04	(69 FR 13765)
Final Action (Sodium Labeling)	03/24/04	(69 FR 13717)
Final Action (Ca/Mg/K/Na)	03/24/04	(69 FR 13725)
Laxative Drug Products (0910–AC85)		
NPRM (Amendment) (Psyllium Granular Dosage Form)	08/05/03	(68 FR 46133)
Merged With 0910-AF38	06/08/04	
Nighttime Sleep Aid Products (0910–AD11)		
Final Action (Amendment)(Warning)	12/06/02	(67 FR 72555)
Ophthalmic Products (0910–AC72)		
NPRM (Emergency First Aid Eyewashes)	02/19/03	(68 FR 7951)
Final Action (Technical Amendment)	02/19/03	(68 FR 7919)
Final Action (Name Change)	06/03/03	(68 FR 32981)
Final Action (Emerg. First Aid Eyewashes) Merged With 0910-AF39	06/08/04	
Oral Health Care Products (0910–AC98)		
ANPRM (Plaque/Gingivitis)	05/29/03	(68 FR 32232)
Merged With 0910-AF40	06/08/04	
Pediculicide Products (0910–AC79)		
NPRM (Labeling Amendment)	05/10/02	(67 FR 31739)
Final Action (Labeling Amendment)	12/31/03	(68 FR 75414)
Salicylate (Reye's Syndrome) (0910–AD13)		
Final Action (Warning)	04/17/03	(68 FR 18861)

HHS—FDA **Completed Actions**

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RIN: 0910-AC58

911. • OVER-THE-COUNTER (OTC) DRUG REVIEW—ANTIDIARRHEAL PRODUCTS

Priority: Routine and Frequent

Legal Authority: 21 USC 321p; 21 USC 351 to 353; 21 USC 355; 21 USC 360a; 21USC 371a; 21 USC 331; 21 USC 360; 21 USC 360b; 21 USC 361; 21 USC 371

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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.

Timetable:

Action	Date	FR Cite
Final Action (Amendment) (Trav. Diar)	05/12/04	69 FR 26301

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: Gerald M. Rachanow, Regulatory Counsel, Division of Over-the-Counter Drug Products, Department of Health and Human Services, Food and Drug Administration, HFD-560, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857
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Related RIN: Split from 0910-AA01

RIN: 0910-AF29

Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA)

Proposed Rule Stage

912. NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS: MEDICAL MALPRACTICE PAYMENTS REPORTING REQUIREMENTS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 11131

CFR Citation: 45 CFR 60.7

Legal Deadline: None

Abstract: This notice of proposed rulemaking (NPRM) proposes to require that, in addition to reporting to the National Practitioner Data Bank medical malpractice payments made where physicians or other health care practitioners are named in medical malpractice actions or claims, judgments, or settlements, payments be reported where they are made for the benefit of physicians or other health care practitioners not named in the judgments or settlements but who furnished or failed to furnish the health careservices upon which the actions or claims were based. The purpose of this NPRM is to prevent the evasion of the medical malpractice payment reporting requirement of the Data Bank through the agreement of the parties to a lawsuit to use the corporate health care entity to "shield" practitioners. It would also require malpractice payers, in very limited circumstances, when it is impossible to identify the practitioner who furnished or failed to furnish the health care services upon which the actions or claims were based, to report why the practitioner could not be identified, and to provide the name of the corporate health care entity.

Timetable:

Action	Date	FR Cite
NPRM	12/24/98	63 FR 71255
Second NPRM	04/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: John M. Heyob, Director, Division of Practitioner Data Banks, Department of Health and Human Services, Health Resources and Services Administration, Suite 300, 7519 Standish Place, Rockville, MD 20957
Phone: 301 443-2300
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RIN: 0906-AA41

913. DESIGNATION OF MEDICALLY UNDERSERVED POPULATIONS AND HEALTH PROFESSIONAL SHORTAGE AREAS

Priority: Substantive, Nonsignificant

Legal Authority: 42 USC 254b; 42 USC 254e

CFR Citation: 42 CFR 5; 42 CFR 51c

Legal Deadline: None

Abstract: This rule would consolidate the process for designating areas of health professional shortage and medical underservice that apply in several department programs, and would improve the criteria for designating medically underserved populations and Primary Care Health Professional Shortage Areas. This notice of proposed rulemaking (NPRM) will address issues raised by comments received in a previous NPRM, dated September 1, 1998.

Timetable:

Action	Date	FR Cite
NPRM	09/01/98	63 FR 46538
Second NPRM	09/00/04	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: None

Agency Contact: Andy Jordan, Acting Chief, Shortage Designation Branch, Department of Health and Human Services, Health Resources and Services Administration, Room 8C26, National Center for Health Workforce Analysis, Bureau of Health Professions, Parklawn Building, Rockville, MD 20857
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RIN: 0906-AA44