

Dated: March 14, 2012.

**Bernadette Dunham,**  
Director, Center for Veterinary Medicine.  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

[Docket No. FDA-2011-N-0003]

#### Oral Dosage Form New Animal Drugs; Phenylpropanolamine

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an original new animal drug application (NADA) filed by Pegasus Laboratories, Inc. The NADA provides for the veterinary prescription use of phenylpropanolamine hydrochloride chewable tablets for the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

**DATES:** This rule is effective March 19, 2012.

**FOR FURTHER INFORMATION CONTACT:** Lisa M. Troutman, Center for Veterinary Medicine (HFV-116), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8322, email: [lisa.troutman@fda.hhs.gov](mailto:lisa.troutman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514, filed NADA 141-324 that provides for the veterinary prescription use of PROIN (phenylpropanolamine hydrochloride) Chewable Tablets for the control of urinary incontinence due to urethral sphincter hypotonus in dogs. The NADA is approved as of August 4, 2011, and the regulations are amended in 21 CFR part 520 to reflect the approval.

A summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment

nor an environmental impact statement is required.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

#### PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

■ 2. Add § 520.1760 to read as follows:

##### § 520.1760 Phenylpropanolamine.

(a) *Specifications.* Each chewable tablet contains 25, 50, or 75 milligram (mg) phenylpropanolamine hydrochloride.

(b) *Sponsors.* See No. 055246 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer 2 mg/kg of body weight twice daily.

(2) *Indications for use.* For the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: March 14, 2012.

**Bernadette Dunham,**  
Director, Center for Veterinary Medicine.  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Chapter I

[Docket No. FDA-2012-N-0222]

#### Revision of Organization and Conforming Changes to Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing this final rule to amend the regulations to reflect organizational change in the Agency and to make other conforming changes. This action is editorial in nature and is intended to improve the accuracy of the Agency’s regulations.

**DATES:** This rule is effective April 1, 2012.

**FOR FURTHER INFORMATION CONTACT:** Vanessa Starks, Human Capital Management, Food and Drug Administration, 19903 New Hampshire Ave., Silver Spring, MD 20903, 301-796-8846.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is issuing this final rule to amend its regulations by updating the organizational information in part 5 (21 CFR part 5).

The portion of this final rule updating the organizational information in part 5, subpart M is a rule of Agency organization, procedure, or practice. FDA is issuing these provisions as a final rule without publishing a general notice of proposed rulemaking because such notice is not required for rules of Agency organization, procedure, or practice under 5 U.S.C. 553(b)(3)(A). For the conforming changes to the other regulations, the Agency finds good cause under 5 U.S.C. 553(b)(3)(B) to dispense with prior notice and comment, and good cause under 5 U.S.C. 553(d)(3) to make these conforming changes effective less than 30 days after publication because such notice and comment and delayed effective date are unnecessary and contrary to the public interest. These conforming changes merely update the footnotes in part 5, subpart M. These changes do not result in any substantive change in the regulations.

##### II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is

not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule simply updates the organizational information, it does not impose any additional costs on industry. Consequently, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

### III. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### IV. Environmental Impact

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

### List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is revised to read as follows:

### PART 5—ORGANIZATION

#### Subparts A–L—[Reserved]

#### Subpart M—Organization

Sec.

5.1100 Headquarters.

5.1105 Chief Counsel, Food and Drug Administration.

5.1110 FDA Public Information Offices.

**Authority:** 5 U.S.C. 552; 21 U.S.C. 301–397.

#### Subparts A–L—[Reserved]

#### Subpart M—Organization

##### § 5.1100 Headquarters.

The Food and Drug Administration consists of the following:

*Office of the Commissioner.*

*Office of Executive Secretariat.*

*Office of the Chief Counsel.*

*Office of the Counselor to the Commissioner.*

*Office of Crisis Management.*

*Office of Emergency Operations.*

*Office of Policy and Planning.*

*Office of Policy.*

*Policy Development and Coordination Staff.*

*Regulations Policy and Management Staff.*

*Regulations Editorial Section.*

*Office of Planning.*

*Planning Staff.*

*Program Evaluation and Process*

*Improvement Staff.*

*Economics Staff.*

*Risk Communications Staff.*

*Office of Legislation.*

*Office of External Affairs.*

*Web Communications Staff.*

*Office of External Relations*

*Communications Staff.*

*Office of Public Affairs.*

*Office of Special Health Issues.*

*Office of Minority Health.*

*Office of Women's Health.*

*Office of the Chief Scientist.*

*Office of Counter-Terrorism and*

*Emerging Threats.*

*Office of Scientific Integrity.*

*Office of Regulatory Science and*

*Innovation.*

*Division of Science Innovation and*

*Critical Path.*

*Division of Scientific Computing and*

*Medical Information.*

*Office of Scientific Professional*

*Development.*

*National Center for Toxicological*

*Research.*

*Office of the Center Director.*

*Office of Management.*

*Office of Scientific Coordination.*

*Office of Research.*

*Division of Biochemical Toxicology.*

*Division of Genetic and Molecular*

*Toxicology.*

*Division of Personalized Nutrition*

*and Medicine.*

*Biometry Branch.*

*Pharmacogenomics Branch.*

*Division of Microbiology.*

*Division of Neurotoxicology.*

*Division of Systems Biology.*

*Office of Operations.*

*Office of Equal Employment*

*Opportunity.*

*Conflict Prevention and Resolution*

*Staff.*

*Compliance Staff.*

*Diversity Staff.*

*Office of Finance, Budget, and*

*Acquisitions.*

*Office of Budget.*

*Office of Acquisitions and Grants*

*Services.*

*Division of Acquisition Operations.*

*Division of Acquisition Support and*

*Grants.*

*Division of Acquisition Programs.*

*Division of Information Technology.*

*Office of Financial Operations.*

*Office of Financial Management.*

*User Fees Staff.*

*Division of Accounting.*

*Division of Budget Execution and*

*Control.*

*Office of Financial Services.*

*Payroll Staff.*

*Division of Payment Services.*

*Division of Travel Services.*

*Office of Information Management.*

*Division of Business Partnership and*

*Support.*

*Division of Chief Information Officer*

*Support.*

*Division of Systems Management.*

*Division of Infrastructure Operations.*

*Division of Technology.*

*Office of Management.*

*Ethics and Integrity Staff.*

*Office of Management Programs.*

*Office of Security Operations.*

*Office of Facilities, Engineering and*

*Mission Support Services.*

*Jefferson Lab Complex Staff.*

*Business Operations and Initiatives*

*Staff.*

*Division of Operations Management*

*and Community Relations.*

*Auxiliary Program Management*

*Branch.*

*Logistics and Transportation*

*Management Branch.*

*Facilities Maintenance and*

Operations Branch.  
Division of Planning, Engineering, and Space Management.  
Planning and Space Management Branch.  
Employee Safety and Environmental Management Branch.  
Engineering Management Branch.  
Office of Library and Employee Services.  
Employee Resource and Information Center.  
FDA Biosciences Library.  
Public Services Branch.  
Technical Services Branch.  
FDA History Office.  
Division of Freedom of Information.  
Division of Dockets Management.  
*Office of Foods.*  
*Center for Food Safety and Applied Nutrition.*  
Office of the Center Director.  
Executive Operations Staff.  
International Staff.  
Office of Management.  
Safety Staff.  
Division of Planning and Budget and Planning.  
Division of Program Services.  
Office of Food Defense, Communication and Emergency Response.  
Division of Education and Communication.  
Division of Public Health and Biostatistics.  
Office of Food Safety.  
Retail Food and Cooperative Program Support Staff.  
Division of Seafood Science and Technology.  
Chemical Hazard Branch.  
Microbiological Hazard Branch.  
Division of Food Processing Science and Technology.  
Process Engineering Branch.  
Food Technology Branch.  
Division of Plant and Dairy Food Safety.  
Plant Products Branch.  
Dairy and Egg Branch.  
Division of Seafood Safety.  
Shellfish and Aquaculture Policy Branch.  
Seafood Processing and Technology Policy Branch.  
Office of Cosmetics and Colors.  
Cosmetic Staff.  
Division of Color Certification and Technology.  
Office of Regulatory Science.  
Division of Analytical Chemistry, Methods Branch.  
Spectroscopy and Mass Spectrometry Branch.  
Division of Microbiology.  
Microbial Methods and Development Branch.  
Molecular Methods and Subtyping Branch.  
Division of Bioanalytical Chemistry.  
Bioanalytical Methods Branch.  
Chemical Contaminants Branch.  
Office of Food Additive Safety.  
Division of Food Contact Notifications.  
Division of Biotechnology and GRAS Notice Review.  
Division of Petition Review.  
Office of Compliance.  
Division of Enforcement.  
Division of Field Programs and Guidance.  
Office of Applied Research and Safety Assessment.  
Division of Molecular Biology.  
Division of Virulence Assessment.  
Division of Toxicology.  
Office of Regulations, Policy, and Social Sciences.  
Regulations and Special Government Employees Management Staff.  
Division of Social Sciences.  
Office of Nutrition, Labeling, and Dietary Supplements.  
Nutrition Programs Staff.  
Division of Dietary Supplement Programs.  
*Center for Veterinary Medicine.*  
Office of the Center Director.  
Office of Management.  
Management Logistics Staff.  
Human Capital Management Staff.  
Program and Resource Management Staff.  
Talent Development Staff.  
Budget Planning and Evaluation Staff.  
Office of New Animal Drug Evaluation.  
Division of Therapeutic Drugs for Non-Food Animals.  
Division of Biometrics and Production Drugs.  
Division of Therapeutic Drugs for Food Animals.  
Division of Human Food Safety.  
Division of Manufacturing Technologies.  
Division of Scientific Support.  
Division of Generic Animal Drugs.  
Office of Surveillance and Compliance.  
Division of Surveillance.  
Division of Animal Feeds.  
Division of Compliance.  
Division of Veterinary Product Safety.  
Office of Research.  
Division of Residue Chemistry.  
Division of Animal Research.  
Division of Animal and Food Microbiology.  
Office of Minor Use and Minor Species Animal Drug Development.  
*Office of Medical Products and Tobacco.*  
Office of Special Medical Programs.  
Advisory Committee Oversight and Management Staff.  
Good Clinical Practice Staff.  
Office of Combination Products.  
Office of Orphan Products  
Development.  
Office of Pediatric Therapeutics.  
*Center for Biologics Evaluation and Research.*  
Office of the Center Director.  
Regulations Policy Staff.  
Quality Assurance Staff.  
Office of Management.  
Regulatory Information Management Staff.  
Division of Planning, Evaluation, and Budget.  
Division of Veterinary Services.  
Division of Program Services.  
Division of Scientific Advisors and Consultants.  
Building Operations Staff.  
Office of Compliance and Biologics Quality.  
Division of Case Management.  
Division of Inspections and Surveillance.  
Division of Manufacturing and Product Quality.  
Office of Biostatistics and Epidemiology.  
Division of Biostatistics.  
Division of Epidemiology.  
Office of Information Management.  
Division of Information Operations.  
Division of Information Development.  
Office of Blood Research and Review.  
Policy and Publications Staff.  
Division of Emerging and Transfusion Transmitted Diseases.  
Division of Hematology.  
Division of Blood Applications.  
Office of Vaccines Research and Review.  
Program Operation Staff.  
Division of Product Quality.  
Division of Bacterial, Parasitic, and Allergenic Products.  
Division of Viral Products.  
Division of Vaccines and Related Product Applications.  
Office of Cellular, Tissue, and Gene Therapies.  
Regulatory Management Staff.  
Division of Cellular and Gene Therapies.  
Division of Clinical Evaluation and Pharmacology/Toxicology.  
Division of Human Tissues.  
Office of Communication, Outreach and Development.  
Division of Disclosure and Oversight Management.  
Division of Manufacturers Assistance and Training.  
Division of Communication and Consumer Affairs.  
*Center for Devices and Radiological Health.*  
Office of the Center Director.  
Regulations Staff.  
Office of Management Operations.  
Division of Ethics and Management Operations.  
Human Resource and Administrative

Management Branch.  
Integrity, Conference and Committee Management Branch.  
Division of Planning, Analysis and Finance.  
Planning Branch.  
Financial Management Branch.  
Office of Compliance.  
Promotion and Advertising Policy Staff.  
Program Management Staff.  
Quality Management Program Staff.  
Division of Bioresearch Monitoring.  
Program Enforcement Branch A.  
Program Enforcement Branch B.  
Special Investigations Branch.  
Division of Risk Management Operations.  
Field Programs Branch.  
Recall Branch.  
Regulatory Policy Branch.  
Division of Enforcement.  
General Surgery Devices Branch.  
Dental Ear, Nose, Throat and Ophthalmic Devices Branch.  
Gastroenterology and Urology Branch.  
General Hospital Devices Branch.  
Division of Enforcement B.  
Radiology, Anesthesiology, and Neurology Devices Branch.  
Cardiac Rhythm and Electrophysiology Devices Branch.  
Vascular and Circulatory Support Devices Branch.  
Orthopedic and Physical Medicine Devices Branch.  
Office of Device Evaluation.  
Program Management Staff.  
Program Operations Staff.  
Pre-Market Approval Staff.  
Investigational Device Exemption Staff.  
Pre-Market Notification Section.  
Division of Cardiovascular Devices.  
Circulatory Support and Prosthetic Branch.  
Interventional Cardiology Devices Branch.  
Pacing, Defibrillators, and Leads Branch.  
Cardiac Electrophysiology and Monitoring Devices Branch.  
Peripheral Scads Vascular Devices Branch.  
Division of Reproductive, Gastro-Renal, and Urological Devices.  
Gynecology Devices Branch.  
Urology and Lithotripsy Devices Branch.  
Gastroenterology and Renal Devices Branch.  
Division of Surgical, Orthopedic, and Restorative Devices.  
General Surgery Devices Branch.  
Restorative Devices Branch.  
Plastic and Reconstructive Surgery Devices Branch.  
Orthopedic Joint Devices Branch.  
Orthopedic Spine Devices Branch.  
Division of Ophthalmic, Neurological, and Ear, Nose, and Throat Devices.  
Intraocular, Corneal, and Neuromaterial Devices Branch.  
Ophthalmic Laser, Neuromuscular Stimulators, and Diagnostic Devices Branch.  
Neurodiagnostic and Neurotherapeutic Devices Branch.  
Ear, Nose, and Throat Devices Branch.  
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices.  
General Hospital Devices Branch.  
Infection Control Devices Branch.  
Dental Devices Branch.  
Anesthesiology and Respiratory Devices Branch.  
Office of Science and Engineering Laboratories.  
Management Support Staff.  
Division of Biology.  
Division of Chemistry and Materials Science.  
Division of Solid and Fluid Mechanics.  
Division of Physics.  
Division of Imaging and Applied Mathematics.  
Division of Solid and Fluid Mechanics.  
Division of Electrical and Software Engineering.  
Office of Communication, Education and Radiation Programs.  
Program Operations Staff.  
Staff College.  
Division of Health Communication.  
Web Communication Branch.  
Risk Communication Branch.  
Division of Small Manufacturers International and Consumer Assistance.  
Technical Assistance Branch.  
International Relations and External Affairs Staff.  
Regulatory Assistance Branch.  
Division of Mammography Quality and Radiation Programs.  
Inspection and Compliance Branch.  
Information Management Branch.  
Diagnostic Devices Branch.  
Electronic Devices Branch.  
Division of Communication Media.  
Television Design and Development Branch.  
Division of Freedom of Information.  
Freedom of Information Branch A.  
Freedom of Information Branch B.  
Office of Surveillance and Biometrics.  
Program Management Staff.  
Division of Biostatistics.  
Cardiovascular and Ophthalmic Devices Branch.  
Diagnostic Devices Branch.  
General and Surgical Devices Branch.  
Division of Postmarket Surveillance.  
Product Evaluation Branch 1.  
Product Evaluation Branch 2.  
Information Analysis Branch.  
MDR Policy Branch.  
Division of Patient Safety Partnership.  
Patient Safety Branch 1.  
Patient Safety Branch 2.  
Division of Epidemiology.  
Epidemiology Evaluation and Research Branch 1.  
Epidemiology Evaluation and Research Branch 2.  
Office of In Vitro Diagnostic Device Evaluation and Safety.  
Division of Chemistry and Toxicology Devices.  
Division of Immunology and Hematology Devices.  
Division of Microbiology Devices.  
Division of Radiological Devices.  
*Center for Drug Evaluation and Research.*  
Office of the Center Director.  
Controlled Substances Staff.  
Safe Use Staff.  
Office of Regulatory Policy.  
Division of Regulatory Policy I.  
Division of Regulatory Policy II.  
Division of Regulatory Policy III.  
Division of Information Disclosure Policy.  
Office of Management.  
Division of Management and Budget.  
Planning and Resource Management Branch.  
Management Analysis Branch.  
Division of Management Services.  
Program Management Services Branch.  
Interface Management Branch.  
Office of Communications.  
Division of Online Communications.  
Division of Health Communications.  
Division of Drug Information.  
Office of Surveillance and Epidemiology.  
Regulatory Science Staff.  
Regulatory Affairs Staff.  
Executive Operations and Strategic Planning Staff.  
Technical Information Staff.  
Program Management and Analysis Staff.  
Project Management Staff.  
Office of Medication Error Prevention.  
Division of Medication Error Prevention and Analysis.  
Division of Risk Management.  
Office of Pharmacovigilance and Epidemiology.  
Division of Epidemiology I.  
Division of Epidemiology II.  
Division of Pharmacovigilance I.  
Division of Pharmacovigilance II.  
Office of Compliance.  
Office of Drug Security, Integrity, and Recalls.  
Division of Import Operations and Recalls.  
Recall Coordination Branch.  
Import Operations Branch.

Division of Supply Chain Integrity.  
Office of Unapproved Drugs and Labeling Compliance.  
Division of Prescription Drugs.  
Prescription Drugs Branch.  
Compounding and Pharmacy Practice Branch.  
Division of Non-Prescription Drugs and Health Fraud.  
Over-the-Counter Drugs Branch.  
Health Fraud and Consumer Outreach Branch.  
Office of Manufacturing and Product Quality.  
Division of International Drug Quality.  
International Compliance Branch I.  
International Compliance Branch II.  
Division of Domestic Drug Quality.  
Domestic Compliance Branch 1.  
Domestic Compliance Branch 2.  
Division of Policy, Collaboration, and Data Operations.  
Regulatory Policy and Communications Branch.  
Drug Surveillance and Data Reporting Branch.  
Division of GMP Assessment.  
Biotech Manufacturing Assessment Branch.  
New Drug Manufacturing Assessment Branch.  
Generic Drug Manufacturing Assessment Branch.  
Office of Scientific Investigations.  
Division of Bioequivalence and Good Laboratory Practice Compliance.  
Good Laboratory Practice Branch.  
Bioequivalence Branch.  
Division of Good Clinical Practice Compliance.  
Good Clinical Practice Enforcement Branch.  
Good Clinical Practice Assessment Branch.  
Division of Safety Compliance.  
Post Market Safety Branch.  
Human Subject Protection Branch.  
Office of New Drugs.  
Pediatric and Maternal Health Staff.  
Program Management Analysis Staff.  
Office of Drug Evaluation I.  
Division of Cardiovascular and Renal Products.  
Division of Neurology Products.  
Division of Psychiatry Products.  
Office of Drug Evaluation II.  
Division of Metabolism and Endocrinology Products.  
Division of Pulmonary, Allergy, and Rheumatology Products.  
Division of Anesthesia, Analgesia, and Addiction Products.  
Office of Drug Evaluation III.  
Division of Gastroenterology and Inborn Effects Products.  
Division of Reproductive and Urologic Products.  
Division of Dermatology and Dental Products.  
Office of Antimicrobial Products.  
Division of Anti-Infective Products.  
Division of Anti-Viral Products.  
Division of Transplant and Ophthalmology Products.  
Office of Drug Evaluation IV.  
Division of Nonprescription Clinical Evaluation.  
Division of Nonprescription Regulation Development.  
Division of Medical Imaging Products.  
Office of Hematology and Oncology Drug Products.  
Division of Oncology Products 1.  
Division of Oncology Products 2.  
Division of Hematology Products.  
Division of Hematology Oncology Toxicology.  
Office of Pharmaceutical Science.  
Program Activities Review Staff.  
Operations Staff.  
Science and Research Staff.  
New Drug Microbiology Staff.  
Office of Generic Drugs.  
Division of Bioequivalence 1.  
Division of Bioequivalence 2.  
Division of Labeling and Program Support.  
Labeling Review Branch.  
Regulatory Branch.  
Review Support Branch.  
Division of Chemistry I.  
Division of Chemistry II.  
Division of Chemistry III.  
Division of Chemistry IV.  
Division of Clinical Review.  
Division of Microbiology.  
Office of New Drug Quality Assessment.  
Division of New Drug Quality Assessment I.  
Branch I.  
Branch II.  
Branch III.  
Division of New Drug Quality Assessment II.  
Branch IV.  
Branch V.  
Branch VI.  
Division of New Drug Quality Assessment III.  
Branch VII.  
Branch VIII.  
Branch IX.  
Office of Testing and Research.  
Division of Drug Safety Research.  
Division of Pharmaceutical Analysis.  
Division of Product Quality Research.  
Office of Biotechnology Products.  
Division of Monoclonal Antibodies.  
Division of Therapeutic Protein.  
Office of Medical Policy.  
Office of Prescription Drug Promotion.  
Division of Consumer Drug Promotion.  
Division of Professional Drug Promotion.  
Office of Medical Policy Initiatives.  
Division of Medical Policy Development.  
Division of Medical Policy Programs.  
Office of Executive Programs.  
Division of Training and Development.  
Training and Development Branch I.  
Training and Development Branch II.  
Division of Executive Operations.  
Division of Advisory Committee and Consultant Management.  
Office of Translational Science.  
Office of Biostatistics.  
Division of Biometrics I.  
Division of Biometrics II.  
Division of Biometrics III.  
Division of Biometrics IV.  
Division of Biometrics V.  
Division of Biometrics VI.  
Division of Biometrics VII.  
Office of Clinical Pharmacology.  
Division of Clinical Pharmacology I.  
Division of Clinical Pharmacology II.  
Division of Clinical Pharmacology III.  
Division of Clinical Pharmacology IV.  
Division of Clinical Pharmacology V.  
Division of Pharmacometrics.  
Office of Counter-Terrorism and Emergency Coordination.  
Office of Planning and Informatics.  
Office of Planning and Analysis.  
Office of Business Informatics.  
Division of Records Management.  
Division of Regulatory Review Support.  
Division of Business Analysis and Reporting.  
Division of Project Development.  
*Center for Tobacco Products.*  
*Office of the Center Director.*  
*Office of Management.*  
*Office of Policy.*  
*Office of Regulations.*  
*Office of Science.*  
*Office of Health Communication and Education.*  
*Office of Compliance and Enforcement.*  
*Office of Global Regulatory Operations and Policy.*  
*Office of International Programs.*  
*Office of Regulatory Affairs.*  
*Office of Resource Management.*  
Division of Planning, Evaluation, and Management.  
Program Planning and Workforce Management Branch.  
Program Evaluation Branch.  
Division of Human Resource Development.  
Division of Management Operations.  
Office of Enforcement.  
Division of Compliance Management and Operations.  
Division of Compliance Policy.  
Division of Compliance Information and Quality Assurance.  
Office of Regional Operations.

Division of Federal-State Relations.  
 State Contracts Staff.  
 State Information Staff.  
 Public Affairs and Health Fraud Staff.  
 Division of Field Science.  
 FERN National Program Branch.  
 Scientific Compliance and Regulatory Review Branch.  
 Laboratory Operations Branch.  
 Division of Import Operations and Policy.  
 Systems Branch.  
 Operations and Policy Branch.  
 Division of Foreign Field Investigations.  
 International Operations Branch.  
 Foreign Food Branch.  
 Foreign Drug Branch.  
 Foreign Devices Branch.  
 Division of Domestic Field Investigations.  
 Team Biologics Staff.  
 National Expert Staff.  
 Domestic Operations Branch.  
 Division of Food Defense Targeting.  
 Office of Criminal Investigations.  
 Mid-Atlantic Area Office.  
 Midwest Area Office.  
 Northeast Area Office.  
 Pacific Area Office.  
 Southeast Area Office.  
 Southwest Area Office.  
 Regional Food and Drug Directors.  
 Regional Field Office, Central Region, Chicago, IL.  
 State Cooperative Programs Staff I.  
 State Cooperative Programs Staff II.  
 Regional Operations Staff.  
 District Office, Baltimore, MD.  
 Compliance Branch.  
 Investigations Branch.  
 District Office, Cincinnati, OH.  
 Compliance Branch.  
 Investigations Branch.  
 Forensic Chemistry Center.  
 Inorganic Chemistry Branch.  
 Organic Chemistry Branch.  
 District Office, Parsippany, NJ.  
 Compliance Branch.  
 Investigations Branch.  
 District Office, Philadelphia, PA.  
 Compliance Branch.  
 Investigations Branch.  
 Laboratory Branch.  
 District Office, Chicago, IL.  
 Compliance Branch.  
 Investigations Branch.  
 District Office, Minneapolis, MN.  
 Compliance Branch.  
 Investigations Branch.  
 District Office, Detroit, MI.  
 Compliance Branch.  
 Investigations Branch.  
 Laboratory Branch.  
 Regional Field Office, Northeast Region, Jamaica, NY.  
 Operations Staff.  
 Intergovernmental Affairs Staff.  
 District Office, New York.

Domestic Compliance Branch.  
 Domestic Investigations Branch.  
 Import Operations Branch (Downstate).  
 Import Operations Branch (Upstate).  
 Northeast Regional Laboratory.  
 Microbiological Science Branch.  
 Food Chemistry Branch.  
 Drug Chemistry Branch.  
 District Office New England.  
 Compliance Branch.  
 Investigations Branch.  
 Winchester Engineering and Analytical Center.  
 Analytical Branch.  
 Engineering Branch.  
 Regional Field Office, Pacific Region, Oakland, CA.  
 District Office, San Francisco, CA.  
 Compliance Branch.  
 Investigations Branch.  
 Laboratory Branch.  
 District Office, Los Angeles, CA.  
 Compliance Branch.  
 Domestic Investigations Branch.  
 Import Operations Branch.  
 District Office, Seattle, WA.  
 Compliance Branch.  
 Investigations Branch.  
 Pacific Regional Laboratory Southwest Los Angeles, CA.  
 Food Chemistry Branch.  
 Drug Chemistry Branch.  
 Microbiology Branch.  
 Pacific Regional Laboratory Northwest Bothell, WA.  
 Chemistry Branch.  
 Microbiology Branch.  
 Seafood Products Research Center.  
 Regional Field Office, Southeast Region, Atlanta, GA.  
 District Office, Atlanta, GA.  
 Compliance Branch.  
 Investigations Branch.  
 District Office, FL.  
 Compliance Branch.  
 Investigations Branch.  
 District Office, New Orleans, LA.  
 Compliance Branch.  
 Investigations Branch.  
 Nashville Branch.  
 District Office, San Juan, PR.  
 Compliance Branch.  
 Investigations Branch.  
 Laboratory Branch.  
 Southeast Regional Laboratory, Atlanta, GA.  
 Chemistry Branch I.  
 Microbiology Branch.  
 Atlanta Center for Nutrient Analysis.  
 Chemistry Branch II.  
 Regional Field Office, Southwest Region.  
 District Office, Dallas, TX.  
 Compliance Branch.  
 Investigations Branch.  
 District Office, Kansas City, MO.  
 Compliance Branch.  
 Investigations Branch.

Science Operations Branch.  
 Total Diet and Pesticide Research Center.  
 District Office, Denver, CO.  
 Compliance Branch.  
 Investigations Branch.  
 Laboratory Branch.  
 Arkansas Regional Laboratory.  
 General Chemistry Branch.  
 Pesticide Chemistry Branch.  
 Microbiology Branch.  
 Southwest Import District Office, Dallas, TX.  
 Compliance Branch.  
 Investigations Branch.

**§ 5.1105 Chief Counsel, Food and Drug Administration.**

The Office of the Chief Counsel's mailing address is White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993.

**§ 5.1110 FDA public information offices.**

(a) *Division of Dockets Management.* The Division of Dockets Management public room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852, Telephone: 301-827-6860.

(b) *Division of Freedom of Information.* The Division of Freedom of Information public room is located in rm. 1050, Element Bldg., 12420 Parklawn Dr., Rockville, MD 20857, Telephone: 301-796-3900.

(c) *Press Relations Staff.* Press offices are located in White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993, Telephone: 301-827-6242; and at 5100 Paint Branch Pkwy., College Park, MD 20740, Telephone: 301-436-2335.

Dated: March 14, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 271**

[FRL-9646-5]

**Ohio: Final Authorization of State Hazardous Waste Management Program Revision**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is granting Ohio final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The agency published a proposed rule on September 14, 2011 at