Special Priorities Assistance; and Appendix IV to part 700: Memorandum of Understanding on Priorities and Allocations Support Between the Department of Commerce and the Canadian Department of Supply and Services, are removed.

Issued: June 5, 1998.

Iain S. Baird,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 98–15410 Filed 6–10–98; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Sulfate, Betamethasone Valerate, and Clotrimazole Ointment

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 abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for the use of gentamicin sulfate, betamethasone valerate, and clotrimazole (Tri-Otic ointment) for the treatment of canine acute and chronic otitis externa associated with yeast and/or bacteria susceptible to gentamicin.

EFFECTIVE DATE: June 11, 1998.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767, filed ANADA 200–229 that provides for the use of gentamicin sulfate, betamethasone valerate, and clotrimazole (Tri-Otic ointment) for the treatment of canine acute and chronic otitis externa associated with yeast and/or bacteria susceptible to gentamicin.

The ANADA is approved as a generic copy of Schering Plough Animal Health Corp.'s NADA 140–896 for OTOMAX® (gentamicin sulfate, betamethasone valerate, and clotrimazole). ANADA 200–229 is approved as of April 8, 1998, and the regulations are amended in 21 CFR 524.1044g to reflect the approval. The basis for approval is discussed in the freedom of information summary. In addition, the agency is amending 21 CFR 510.600(c)(1) and (c)(2) to reflect a change of sponsor's name and address.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(d)(1) 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.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 524

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 parts 510 and 524 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) in the entry for ''Med-Pharmex, Inc., Biomed Laboratories'' and in the table in paragraph (c)(2) in the entry for ''051259'' by revising the sponsor name and address to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * *
Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861	051259
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
051259	Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861
* * *	* * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.1044g [Amended]

4. Section 524.1044g *Gentamicin sulfate, betamethasone valerate, clotrimazole ointment* is amended in paragraph (b) by removing ''000061'' and adding in its place ''000061 and 051259''.

Dated: May 27, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–15554 Filed 6–10–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[FRL–6109–7]

Removal of the Prohibition on the Use of Point of Use Devices for Compliance with National Primary Drinking Water Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Today's action removes the prohibition on point of use (POU) devices as compliance technologies for National Primary Drinking Water Regulations that is set forth in the Code of Federal Regulations in section 141.101. EPA is removing the prohibition on the POU devices because it conflicts with section 1412(b)(4)(E)(ii) of the Safe Drinking Water Act (SDWA) as amended on August 6, 1996. No other part of section 141.101 is affected by today's action.

DATES: This action is effective June 11, 1998.

FOR FURTHER INFORMATION CONTACT: The Safe Drinking Water Hotline, toll free (800) 426–4791, or Tara Chhay Cameron; Targeting and Analysis Branch; Office of Ground Water and Drinking Water; EPA (4607), 401 M Street, S.W., Washington, DC 20460; telephone (202) 260–3702.

SUPPLEMENTARY INFORMATION:

Table of Contents

A. Regulated Entities

Entities potentially regulated by this action are those which meet the criteria of the Public Water Systems (PWS) definition. Regulated categories and entities include:

Category	Example of Regulated Entities
Industry	Public Water Systems

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the type of entities that EPA is now aware of that could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria in §§ 141.2, 142.2, 142.3, and 142.10 of title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Explanation of Today's Action

On July 8, 1987 (52 FR 25716) EPA promulgated a requirement in section 40 CFR 141.101 that public water systems shall not use POU devices to achieve compliance with a maximum contaminant level (MCL) of a National Primary Drinking Water Regulations.

On August 6, 1996, amendments to the SDWA were enacted into law. Section 1412(b)(4)(E)(ii) of the SDWA, as amended, authorizes the use of POU devices by public water systems to comply with an MCL under certain circumstances. In order to make the regulatory provisions consistent with the new statutory language, with today's action, EPA removes the prohibition on the use of POU devices by public water systems to comply with an MCL. No other provision of section 141.101 is affected by this action.

C. Administrative Requirements

1. Executive Order 12866

Under Executive Order 12866 (58 FR 51,735 (October 4, 1993)), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(a) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(b) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(c) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(d) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

2. Regulatory Flexibility Act

The Agency has determined that the rule being issued today is not subject to the Regulatory Flexibility Act (RFA), which generally requires an Agency to conduct a regulatory flexibility analysis of any significant impact the rule will have on a substantial number of small entities. By its terms, the RFA applies only to rules subject to notice and comment rulemaking requirements