DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91F–0392]

Phoenix Medical Technology, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a food additive petition (FAP 1B4273) proposing that the food additive regulations be amended to provide for the safe use of 2,4,4'-trichloro-2-hydroxydiphenyl ether as an antimicrobial agent in the manufacture of polyvinyl chloride gloves for food-contact use.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 6, 1991 (56 FR 56656), FDA announced that a food additive petition (FAP 1B4273) had been filed by Phoenix Medical Technology, Inc., P.O. Box 346, Andrews, SC 29510. The petition proposed to amend the food additive regulations to provide for the safe use of 2,4,4'-trichloro-2-hydroxydiphenyl ether as an antimicrobial agent in the manufacture of polyvinyl chloride gloves for food-contact use.

On August 3, 1996, the Food Quality Protection Act (Pub. L. No. 104–170), which amended the Federal Food, Drug, and Cosmetic Act (the act), transferred from FDA the regulatory authority over the petitioned use of this substance as a food additive under section 409 (21 U.S.C. 348) of the act to the Environmental Protection Agency (EPA) as a pesticide chemical under section 408 (21 U.S.C. 346a) of the act, as amended.

In response to a request by the petitioner, which was prompted by the change in regulatory authority over the antimicrobial substance that is the subject of this petition, FDA transferred the records for Food Additive Petition 1B4273, including all of FDA's reviews of information in the petition, to EPA.

Phoenix Medical Technology, Inc., has now withdrawn the petition.

Dated: May 21, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–15766 Filed 6–12–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0487]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Abbreviated New Drug Application Regulations, Patent and Exclusivity Provision'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 12, 1997 (62 FR 65431), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0305. The approval expires on May 31, 2001.

Dated: June 5, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15768 Filed 6–12–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 89N–0474]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Specific Requirements on Content and Format of Labeling for Human Prescription Drugs, Addition of 'Geriatric Use' Subsection in the Labeling'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, August 27, 1997 (62 FR 45313), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0370. The approval expires on May 31, 2001.

Dated: June 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15813 Filed 6–12–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0365]

Revised Guidance for Industry and Reviewers on Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry and reviewers entitled ''Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act.'' The guidance clarifies the processes that will be followed in implementing this section of the Food and Drug Administration Modernization Act of 1997 (Modernization Act). This revision includes clarification of the procedures applicable to bulk drug substances for products previously regulated under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

For general information regarding this notice: Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400.

For issues on bulk drug substance procedures: Gordon R. Johnston, Center for Drug Evaluation and Research (HFD–601), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5845.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a revised guidance for industry and reviewers entitled ''Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act.'' Section 125 of title I of the Modernization Act (Pub. L. 105–115), signed into law by President Clinton on November 21, 1997, repealed section 507 of the act (21 U.S.C. 357). As a result of the repeal of section 507 of the act, which took effect immediately, several of the agency's administrative processes for reviewing and approving antibiotic drug applications had to be changed. This guidance document, intended to clarify several of the administrative processes that will be followed in implementing section 125 of the Modernization Act, has now been revised to include the procedures applicable to bulk drug substances for products previously marketed under section 507 of the act.

This revised guidance document is a level 1 guidance document consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the implementation of the repeal of section 507 of the act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 8, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–15769 Filed 6–12–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Disadvantaged Assistance Tracking and Outcome Report (New)

The Health Careers Opportunity Program (HCOP) and the Centers of Excellence (COE) Program (sections 740 and 739 of the Public Health Service (PHS) Act, respectively) provide opportunities for under-represented minorities and disadvantaged individuals to enter and graduate from health professions schools. The Disadvantaged Assistance Tracking and Outcome Report (DATOR) will be used to track program participants through the health professions pathway to a health professions practice outcome. The current inability to track students' education progression in the health professions is a major impediment in assessing the outcome of these programs. There is no identifier used that transcends the various education levels, professional disciplines, and educational institutions.

The DATOR, to be completed annually by HCOP and COE grantees, includes basic data on student participants (name, social security number, gender, race/ethnicity; targeted health professions, their status in the educational pipeline from pre-professional through professional training; financial assistance received through the grants funded under sections 739 and 740 of the PHS Act in the form of stipends, fellowships or per diem; and their employment or practice setting following their entry into the health care work force).

The proposed reporting instrument is not expected to add significantly to the grantees reporting burden. This reporting instrument complements the grantees internal automated reporting mechanisms of using name and social security number in tracking students. Estimates of annualized burden are as follows: