

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Phoenix Medical Technology, Inc., has now withdrawn the petition.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

BILLING CODE 4160-01-F

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]

BILLING CODE 4160-01-F

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]

BILLING CODE 4160-01-F

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.