EPA737-N-94-010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 6, 1994

PESTICIDE REGULATION (PR) NOTICE 94-6

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Pesticide Products Registered for Use on Humans to Control Lice (Pediculicides)

This notice alerts pesticide registrants to a rule issued by Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act (FFDCA) establishing conditions for safe and effective use of pediculicide drug products (including pesticide products) for over-the-counter (OTC) human use. As a result of the FDA rule pesticide products containing the active ingredients pyrethrins and piperonyl butoxide and labeled solely for use on humans as a pediculicide (treatment of head, pubic (crab) and body lice) will no longer be regulated by EPA. Specifically, aerosol formulations of pediculicides are exempt from regulation under FIFRA as of June 14, 1994 and non-aerosol formulations will be exempt from regulation as of December 14, 1994. In addition this notice discusses actions registrants may take prior to December 14, 1994 to prepare for compliance with the FDA rule and also remain in compliance with FIFRA.

The FDA rule was published in the Federal Register of December 14, 1993 (58 FR 65451). Upon the effective dates of this rule (i.e., June 14, 1994 and December 14, 1994) regulatory jurisdiction for OTC human pediculicides will rest fully with the FDA. No response to this notice is required unless a registrant wishes to sell a product bearing FDA labeling prior to December 14, 1994 (See Section III).

I. BACKGROUND

There are certain pesticide products that fall within the statutory definition of "drug" in the FFDCA and as such are also subject to the jurisdiction of the FDA. In the Federal Register of November 5, 1979 (44 FR 63749) EPA issued a final regulation to clarify its policy regarding the registration of pesticide products (which include pediculicide products) that are not new drugs. Basically, EPA has jurisdiction over pesticide products marketed OTC and used as pediculicides under FIFRA whereas FDA has jurisdiction over pediculicide drug products under FFDCA. 40 CFR

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Section 152.20(b) of EPA's regulations provides that a pesticide, such as pyrethrins, is exempt from requirements of FIFRA if the product is offered solely for human use and also is a new drug within the meaning of FFDCA section 201(p) or is a product that has been determined not to be a new drug by the Secretary of Health and Human Services by a regulation establishing conditions for use of the product.

Prior to December 14, 1993 FDA had not declared pediculicide products containing pyrethrins to be new drugs nor established conditions for use of these products in a regulation. Therefore, EPA had jurisdiction on such products. However, on December 14, 1993, FDA issued a final rule establishing conditions for use of these products which effectively removed pediculicide drug products containing pyrethrins and piperonyl butoxide from the requirements of FIFRA. Upon the effective date of the final rule (i.e., December 14, 1994) regulatory jurisdiction of OTC human pediculicides will rest fully with the Food and Drug Administration. Firms that market non-aerosol OTC human pediculicides must comply with the FDA final rule with respect to labeling, formulation, etc., by that effective date. The only acceptable OTC pediculicide products for human use under this final rule are combinations of pyrethrum extract (0.17 to 0.33 percent) with piperonyl butoxide (2 to 4 percent) in a nonaerosol dosage form. Under the same rule, any aerosol OTC pediculicides may no longer be marketed after June 14, 1994, unless they are the subject of an approved New Drug Application.

According to Agency records there are twenty-five (25) products registered as pediculicides for use on humans, one of which is an aerosol formulation.

II. DISCUSSION

On April 22, 1994, the Nonprescription Drug Manufacturers Association (NDMA) submitted a petition entitled "Petition for the Administrative Coordination of Transfer of Regulatory Authority from EPA to FDA for OTC Pediculicide Products." NDMA also filed the same petition with FDA requesting similar action. NDMA is a trade association that represents OTC pediculicide manufacturers. Basically, the petition informed EPA that (1) firms subject to the FDA rule needed at least one and one-half years from December 14, 1993 for a smooth transition from EPA to FDA regulation for OTC pediculicide drug products; (2) firms needed EPA approval of a time period effective as soon as possible and ending on December 14, 1994, during which time the production and shipment into interstate commerce of OTC pediculicide products that bear FDA mandated labeling would be deemed in compliance with EPA regulations; and (3) firms needed EPA to inform their field compliance authorities and state authorities of the regulatory status of these products (i.e., EPA permitting future FDA mandated labeling during the period of EPA compliance authority).

In support of these actions, the NDMA petition included a

comparison of current EPA and FDA required labeling. The comparison demonstrated that the labeling currently approved by EPA was substantively the same as that which would be required by FDA after December 14, 1994 with respect to information needed by the user to use the product safely and effectively. Thus, use of FDA mandated labeling prior to the administrative transfer date and during the time of EPA authority over OTC pediculicide products would not represent a safety or efficacy problem. In addition, EPA allowance to permit FDA mandated labeling for OTC pediculicides prior to December 14, 1994 would help significantly in minimizing the possibility of excess inventory after the compliance date of the FDA final rule and assure that the OTC supply of available product for lice infestation is fully available for the users during the 1994 season.

The EPA has determined that currently EPA registered OTC pediculicide products that bear FDA mandated labeling per the FDA OTC final rule would be in compliance with Federal regulation until December 14, 1994 provided certain actions are taken with respect to the FDA label.

EPA will allow the use of FDA mandated labeling provided:

- Registrants who want to market pediculicides with FDA labeling prior to December 14, 1994 notify EPA in writing that the labeling submitted in conjunction with their registration is in full compliance with the FDA rule published in the Federal Register of December 14, 1993 (58 FR 65451);

- Registrants submit such labeling along with their notification;

- The labeling bears the current EPA Registration Number and the misuse statement "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling."

With respect to these changes and existing stocks, FDA does not object to OTC pediculicide drug products conforming with the final FDA rule and also containing EPA required labeling for a period of 1 year after the effective date of the final rule on December 14, 1994.

III. WHAT REGISTRANTS SHOULD DO

The following actions should be taken only if a registrant wishes to market an EPA registered product bearing FDA labeling prior to December 14, 1994:

A. Ensure that labeling in conformance with the FDA final rule bears the following:

1. EPA Registration Number

2. The misuse statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

B. Submit a Notification (in accordance with the procedures outlined in PR Notice 88-6) which states, "I certify that the enclosed labeling is in compliance with the FDA final rule published in the Federal Register in December 14, 1993 (58 FR 65451) and bears the label revisions described in PR Notice 94-6 ." A copy of the labeling should be enclosed.

IV. EFFECTIVE DATES

This notice is effective immediately.

V. MAILING ADDRESS

Registrants should send notifications and labeling to the following address:

U. S. Postal Service Deliveries

Document Processing Desk (NOTIF)
Office of Pesticide Program (7504C)
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, DC 20460-0001

Personal/Courier Service Deliveries (Mon.-Fri., 8:00 a.m. to 4:30 p.m., except federal holidays)

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

VI. FOR FURTHER INFORMATION

If you have questions regarding this notice, contact George LaRocca, Product Manager 13, Registration Division at (703) 305-6100.

Sincerely,

Stephen L. Johnson, Director
Registration Division