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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUN 18 1982

PR NOTICE 82-2

NOTICE TO MANUFACTURERS, FORMULATORS, DISTRIBUTORS,
AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticides

SUBJECT: Change in procedures for approval of applications

This Notice revises Agency procedures with respect to the following:

1. Submission and review of final printed labeling before registration. The Agency will no longer require approval of final printed labeling before registration, but will require submission of such labeling after registration. The Agency will not approve or return a stamped copy of final printed labeling to the applicant.

2. The applicant's written agreement to the conditions imposed upon the registration. Certain applicants, primarily those having "me-too" products or substantially similar uses to which only general conditions are applicable, will no longer be required to agree in writing to the conditions imposed upon the registration.

These changes affect all current and future registrants, and are effective for all new and amended applications approved as of August 1, 1982. This is a notice of changed procedure only; no response to this Notice is required.

I. BACKGROUND

Since 1975, EPA has required that both draft labeling and final printed labeling be reviewed and approved by the Agency before registration or amended registration was granted. The normal procedure has been that the applicant's typescript or mockup label is provisionally approved by a provisional acceptance (PA) letter, often with required labeling changes. The applicant revises his label, and upon Agency approval of the final printed label, is free to market his product.

Additionally, in 1979, the Agency began using the PA letter as the means of notifying applicants of the conditions that must be met under conditional registration. The submission of final printed labeling was

then coupled with the applicant's acknowledgement of and acquiescence to the conditions stated in the PA letter.

Historically, Agency review of final printed labeling has consumed an average 2-4 weeks of processing time, including receipt, review, and response, although in some cases this time has been extended to as much as 12 weeks. Registrants have indicated to the Vice President's Task Force on Regulatory Relief that they desired relief in this area, that they were prepared to assume the additional responsibility for producing accurate final printed labeling if it would result in faster decision-making by the Agency. The Agency believes that the procedural changes in this Notice will accomplish these objectives without jeopardizing protection of human health and the environment.

II. FINAL PRINTED LABELING

1. The Agency will no longer routinely require the submission of final printed labeling before approval of registration. Except as stated in 5. below, an application will be approved on the basis of draft labeling. A copy of the draft labeling stamped "Accepted" will be sent to the applicant. Product registration will be effective on the date the Notice of Registration is sent to the applicant. (References to "registration," or "Notice of Registration" in this document should be read to include amended registration, and approval letters for amendments.)

2. The Agency will require, as a condition of registration, that:

a. The registrant make the labeling changes specified in the Notice of Registration before the product is released for shipment; and

b. The registrant submit a copy of his final printed labeling before the product is released for shipment.

3. Final printed labeling will not be approved by the Agency, nor will a stamped copy be returned to the registrant. The Agency will, however, selectively audit final printed labeling to ensure compliance by registrants.

4. After making the required labeling changes, the registrant may distribute the product in commerce. He need not wait until the final printed label has been received by the Agency.

5. The Agency will require final printed labeling on a case-by-case basis prior to granting registration if extensive revisions are necessary, or if the registrant has previously failed to make required changes.

III. AGREEMENT TO CONDITIONS OF REGISTRATION

1. If the Agency imposes only conditions that are generally applicable to all similar products, including the requirement to submit data at an unspecified future date, the requirement to submit production figures for new uses, and the labeling requirements in II.2. above, the Agency will state the conditions of registration in the Notice of Registration.

a. The registrant will not be required to acknowledge in writing his acceptance of these conditions.

b. The registrant's release for shipment, or distribution of the product in commerce, will constitute acceptance of the conditions specified in the Agency's approval notice.

2. If the Agency imposes conditions that require the submission of specific data within a given time period, or other conditions that pertain uniquely to the product in question, the Agency will continue to use the current two-step approval system.

a. The applicant will be notified of the conditions of the registration via a PA letter, and will be required to respond to the Agency with his agreement to those conditions.

b. The product will not be registered until the Agency has received the applicant's agreement to the specific conditions set out in the PA letter.

c. The applicant will not, however, be required to submit his final printed label before registration. He may respond immediately to the PA letter with his agreement to the conditions of the registration, and submit his final printed label at any time before the product is released for shipment.

IV. EFFECT OF CHANGES

The effect of these changes is that new "me-too" products and amendments to add substantially similar uses to such products may generally be registered after a single review cycle, culminating in the issuance of a Notice of Registration setting out conditions for registration.

On the other hand, new uses and new chemicals being conditionally registered will generally have to undergo an additional cycle so that the applicant is given the opportunity to review the conditions being imposed on the registration, and to agree to them.

Regardless of whether the applicant must respond to the conditions of registration, however, he generally will not be required to submit his final printed label to the Agency until after the product has been registered.

The Agency's response to the application will clearly indicate whether the application has been approved (a Notice of Registration will be issued) or whether the applicant must submit a further response to conditions of registration (a PA letter will be sent).

V. ENFORCEMENT

1. If a registrant fails to submit his final printed labeling prior to the product's release for shipment, as provided in II.2.b. above, the Agency may propose to cancel the registration under FIFRA sec. 6(e).

2. If the registrant distributes a product that bears labeling contrary to that required and agreed to, the Agency may propose to cancel the registration under FIFRA sec. 6(e). Moreover, if the product released for shipment bears incorrect or otherwise deficient labeling, the registrant may be in violation of FIFRA sec. 12(a)(1)(B) (claims differ from registered labeling), or sec. 12(a)(1)(E) (misbranding).

VI. EFFECTIVE DATE

The changes in this Notice will be effective for all applications approved after August 1, 1982. The Agency intends to revise its current registration regulations [40 CFR 162.6(b)] to reflect these procedural changes.

VII. FURTHER INFORMATION

For further information on this Notice, contact Jean Frane, Registration Division at (703) 557-0593, or, if a specific product is involved, the Product Manager responsible for that product.

Edwin L. Johnson

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