March 31, 1993

PESTICIDE REGULATION (PR) NOTICE 93-6

Notice to Manufacturers, Producers, Formulators and Registrants of Pesticides

ATTENTION: Persons Responsible for the Federal Registration of Pesticides

SUBJECT: False or Misleading Statements Related to Efficacy; Revision of PR Notice 91-7

This notice clarifies EPA's policy with respect to certain claims of heightened efficacy for pesticide products and supersedes PR Notice 91-7.

I. BACKGROUND

PR Notice 91-7 described the regulatory background for EPA's policy to prohibit the use of claims of heightened efficacy such as "extra strength" and "industrial strength." While the agency has applied this policy since the mid-1980's, many products first registered prior to that time continue to carry such claims. The purpose of PR Notice 91-7 was to bring all labels into line with current policy.

The basis provided by PR Notice 91-7 for the agency's policy of prohibiting claims of heightened efficacy was threefold. First, when EPA reviewed the current use of such claims, it found that products bearing such claims were generally no different from other products in either strength or percentage of active ingredient. However, even if such products could be proven to be more efficacious than competing products, the agency believes that the use of claims such as "extra strength" is misleading because such claims provide no basis for comparison and are therefore not capable of being substantiated.

Second, because such claims appear on EPA approved labeling, they could mislead consumers to believe that EPA has assessed such efficacy claims, or created efficacy classifications for these products when in fact EPA does neither. The agency believes there is a strong potential for misunderstanding because EPA approves the classification of certain public health related pesticides, such as disinfectants and sterilants, on the basis of efficacy.

Third, EPA believes that certain claims of heightened efficacy (such as "professional strength") may at times be confused with required statements for restricted use pesticides which permit sale to and use only by certified applicators. Because of the risks posed by restricted use pesticides, the agency believes it is important that the distinction between restricted use and unrestricted pesticides remains clear to retailers, purchasers and applicators.

Based on comments received on PR Notice 91-7, the agency has determined that additional guidance in this notice is necessary to help registrants conform to the agency's policy.

II. POLICY

The EPA believes that certain claims of heightened efficacy are false or misleading. The EPA considers pesticide products bearing such claims to be misbranded and therefore not consistent with the requirements of FIFRA. Accordingly, such claims should be removed from the label and labeling of pesticide products.

III. APPLICABILITY OF POLICY

This policy applies to any statement, design, graphic representation or brand name which implies claims of heightened efficacy of a pesticide product by itself or as compared to another product or device. Examples of such claims include, but are not limited to: "professional strength," "extermination strength," "hospital strength," "industrial strength," "institutional strength," "super strength," "ultra strength," "maximum strength," "maximum efficacy," "extra strength," "double-strength," "triple-strength," "hospital grade," "high potency" and "high-powered." However, this policy does not apply to:

1. True, non-misleading claims regarding the effectiveness of a product against target pests. Examples of such claims include but are not limited to: "kills roaches," "controls target pests," "laboratory tests show the product provides effective pest control for X months" and "kills pests on contact." However, such claims may not be exaggerated or used in a way that would make them misleading.

2. Terms which function only to define a use site and which are not themselves claims of heightened efficacy, provided that such terms are not used in a manner that is misleading. For example, the term "hospital use" may be acceptable as long as it is not used in the product name or highlighted on the label to the exclusion of other acceptable use sites.

3. Terms which describe a specific level of efficacy and which are standard EPA-accepted claims such as "bacteriostatic," "sanitizer," "disinfectant" and "sterilant."

4. Product brand names in which a superlative term is qualified by the term "Brand." Examples include: "Super Brand," "Superior Brand," "Ultra Brand," "Ultimate Brand," "Maximum Brand," "Perfect Brand" and "Ideal Brand." However, brand names that function as unqualified claims of heightened efficacy may be considered misleading whether or not they are qualified by the term "brand."

The Agency will use the above policy and applicable law and regulations to make decisions on whether specific claims are false or misleading. The Agency will consider the policy's applicability to the facts and the underlying validity of the policy in making such decisions.

IV. IMPLEMENTATION OF POLICY

Registrants should remove false or misleading claims which are contained in use directions by submitting an amendment (EPA application form 8570-1, five copies of draft label or labeling, and inserting in the block headed "Nature of the Action" a phrase such as "Amendment in accordance with PR Notice 93-6"). Applications for amendment should be sent to the appropriate Product Manager (see address listed in PR Notice 91-3).

Registrants should remove false or misleading claims which are not contained in use directions, such as in the brand name or in places on the label other than the use directions, by submitting a notification (i.e., EPA application form 8570-1 and one copy of the label or labeling, and inserting in the block headed "Nature of the Action" a phrase such as "Notification in accordance with PR Notice 93- ") addressed to the appropriate Product Manager.

All products distributed or sold by registrants and supplemental registrants (i.e. distributors) after April 21, 1994 should bear labeling which is consistent with this notice and complies with FIFRA. It is the responsibility of registrants to submit applications or notifications in adequate time to meet this deadline. All products distributed or sold by persons other than registrants or supplemental registrants after April 21, 1996 should bear correct labeling. After these dates, the agency may either issue a Notice of Intent to Cancel or bring enforcement action against a product bearing false or misleading claims covered by this notice.

You may contact Jeff Kempter (703-305-5448) if you have questions about this notice.

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Lawrence E. Culleen, Acting Director
Registration Division