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CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

August 8, 2002

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0058: Pediculicide Drug Products
for Over-the-Counter Human Use

Dear Sir or Madam:

On May 10, 2002, the Food and Drug Administration (FDA) proposed in the *Federal Register* an amendment to the final monograph for over-the-counter (OTC) pediculicide drug products that would revise the statement of identity, warnings, directions, and other required statements on the labeling of those products. The proposed rule also makes minor revisions in the indications section to conform with the new labeling format for OTC drug products (21 CFR 201.66). FDA states two reasons for the proposed amendment: to make pediculicide drug product labels conform with the new labeling format, and to increase the probability of treatment success.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national association representing manufacturers and distributors of OTC drug products and dietary supplements. CHPA members account for over 90 percent of OTC drugs marketed in the United States, including many pediculicide products. Accordingly, the Association has important interest in this matter and welcomes the opportunity to comment on the proposed rule. CHPA has particular interest in matters regarding labeling improvements that assist consumers to use OTC drug products correctly. CHPA members have been working for many years to make their product labels more consumer-friendly and worked cooperatively with FDA in the development of the 1999 OTC labeling rule.

02N-0058

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Following are CHPA comments and recommendations on:

- Statement of Identity
- Format Changes
- Revised Directions
- Other Label Information
- Needed Consistency Between Monograph and NDA Labeling

A. Statement of Identity

CHPA supports FDA's proposed removal of the term "pediculicide" from the statement of identity (Sec 358.650 (a)). "Lice treatment" without the additional word "pediculicide," which many persons may not understand, is sufficient as a clear statement of identity for consumers and is consistent with general readability principles of reducing the number of syllables in descriptive words to make them easier to comprehend.

B. Format Changes

FDA's proposed simplification of the indications section under the heading "Uses" is also likely to assist consumer understanding. CHPA supports other proposed formatting changes as well, specifically the use of subheadings and bullets in conformance with the new labeling format in 21 CFR 201.66. Such warning subheadings as "Do not use," "Ask a doctor before use," "When using this product," and "Stop use and ask a doctor if" are helpful to consumers and increase the probability of correct use of the products. CHPA was a proponent of these formatting elements when the new labeling format rule for OTC products was under development.

Revised, shortened, bulleted warning statements under appropriate subheadings, as proposed by FDA, are more likely to be easily read and understood by consumers. Examples are: "Do not use [bullet] near eyes [bullet] inside nose, mouth, or vagina" and "When using this product [bullet] keep eyes tightly closed and protect eyes with a washcloth or towel."

C. Directions

FDA proposed to amend the label "Directions" to contain more information. The proposed additional labeling language is, however, so extensive that it cannot be accommodated on pediculicide product carton labels. Essential treatment directions should be on the outer label, but lengthy, detailed directions for environmental control and combing and additional statements described as "other information" would be more appropriately provided in a package insert. Specifically, the proposed new information in Sec. 358.650 (d)(3) regarding inspection of each household member and 358.650 (d)(5) regarding removing lice and their eggs should be part of a package insert rather than printed on the outer carton. Strictly speaking, the information is about use of such auxiliary devices as a comb, a throwaway glove, tissue, and a plastic bag rather than being required directions for using the drug product. Consumers do not need to be able to read those entire detailed instructions at the point of purchase. They should be directed to the insert by a statement on the package, such as "See brochure inside for other important information to help get rid of lice." A statement about use of a comb should be allowed optionally on the outer label, and that statement could incorporate a reference to a comb provided in the package, and should instruct consumers to see the package insert for complete directions.

The slightly revised directions in new Sec. 358.650 (d)(4) for either shampoo or non-shampoo products should be on the outer package label under the subheading "Treat" as well as being included as part of the directions in the package insert. The other important direction statements that should be on the outer package label as well as in the package insert are in new Sec. 358.650 (d)(6), (7), and (8). They are "a second treatment must be done in 7 to 10 days to kill any newly hatched lice," "if infestation continues, see a doctor for other treatments," and "children under 2 years." [in bold type] "ask a doctor." The last of these will be more likely to be read as part of concise directions on the package dealing specifically with use of the pediculicide drug product itself.

D. Other Label Information

CHPA disagrees with FDA's proposed change from 2 weeks (as is currently specified in product labeling) to 4 weeks for the time items should be sealed in a plastic bag if they cannot be washed and are not dry cleaned (Sec. 358.650 (e)(1)). The agency gave no rationale for doubling the time, and pediculicide companies know of no evidence showing items need to be sealed in for more than 2 weeks to prevent their reinfestation. CHPA recommends that "2 weeks" be retained in the information for sealed storage.

Consumers need product-specific information to use an OTC pediculicide correctly and have the best probability of treatment success. FDA should explicitly state in the amended final monograph for OTC pediculicide drug products that truthful and non-misleading special instructions specific to a particular product are allowed on the product package label. Such instructions might be, for example, to "shake the product well before use" or "apply to dry hair," or they might concern proper conditions for storage. It would make sense for FDA to state that such information is intended to enhance the product-specific directions. The agency should give examples and specifically state that a reasonable degree of flexibility will be given to companies choosing to amplify the directions appropriately.

E. Needed Consistency Between Monograph and NDA Labeling

The rule proposed by FDA also presents an important matter of procedure, fairness, and avoidance of consumer confusion. Some OTC pediculicide drug products are marketed under the Final Monograph and others are marketed under New Drug Applications (NDAs) sometimes under the same brand name. The proposed rule applies only to the monograph products and does not provide for managing the inconsistency that would be produced between monograph and NDA products with different labeling. FDA should coordinate label changes for OTC products within a therapeutic category. Monograph labeling that is inconsistent with NDA labels for the same category of products could cause consumer confusion. FDA should provide for expedited implementation of revised NDA labeling at the same time as the effective date for a final amendment requiring labeling changes for OTC monograph products within the same category.

SUMMARY

CHPA supports FDA's proposed changes for the statement of identity and the indications section on the labels of OTC pediculicide drug products. The simplified, straightforward wording and clear formatting should make the products even easier for consumers to use correctly. FDA's proposed revised, shortened, bulleted warning statements under appropriate subheadings are similarly more likely to be read, easily understood, and heeded.

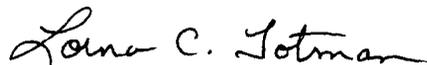
FDA should not require extensive information about procedures for environmental control and combing to remove lice eggs on the outer labels on OTC pediculicide drug products. Concise essential treatment directions without intervening paragraphs of other information on the outer label are more likely to be read, which will increase the probability of treatment success. The more extensive accompanying information should be included with the treatment directions in a package insert, and the outer package should have a statement directing consumers to the important information in the insert.

The 4 weeks specified in the revised information about sealed storage of items to prevent their reinfestation is needlessly long. FDA should retain the "2 weeks" that is recommended in current pediculicide labeling.

FDA should state in the amended final monograph for OTC pediculicide drug products that certain product-specific statements are allowed on the product package label.

FDA should coordinate consistent labeling changes for pediculicide products that are marketed under NDAs at the same time labels are changed for monograph products in that therapeutic category.

Sincerely,



Lorna C. Totman, Ph.D., DABT
Director of Scientific Affairs

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