

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 358

[Docket No. 02N-0058]

RIN 0910-AA01

Pediculicide Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the final monograph for over-the-counter (OTC) pediculicide drug products to revise labeling for the statement of identity, warnings, directions, and other required statements. Pediculicide drug products are used for the treatment of head, pubic (crab), and body lice. This proposal is part of FDA's ongoing review of OTC drug products.

DATES: Submit written or electronic comments by [*insert date 90 days after date of publication in the **Federal Register***]; written comments on the agency's economic impact determination by [*insert date 90 days after date of publication in the **Federal Register***]. See section VIII for the effective and compliance dates of any final rule that may publish based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Michael T. Benson, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of December 14, 1993 (58 FR 65452), the agency published a final rule in the form of a final monograph in part 358 (21 CFR part 358, subpart G) establishing conditions under which OTC pediculicide drug products are generally recognized as safe and effective. The effective date of the final rule was December 14, 1994. Since that time, the agency has determined that labeling in the statement of identity, warnings, directions, and certain other required statements in the pediculicide monograph should be amended to increase the probability of treatment success with these products.

In the **Federal Register** of March 17, 1999 (64 FR 13254), the agency published a final rule for standardized format and content requirements for OTC drug product labeling in § 201.66 (21 CFR 201.66). In that same final rule (64 FR 13254 at 13296), the agency amended the final monograph for OTC pediculicide drug products and removed the requirement in § 358.650(d)(1) that the direction “Important: Read warnings before using” be printed in all capital letters. The sentence now needs only to appear in boldface type with only the first letter in the word “Important” and the word “Read” capitalized.

II. The Agency’s Proposal*A. Introduction*

The agency is proposing to revise the statement of identity, warnings, directions, and certain other required statements in the monograph for OTC pediculicide drug products for two reasons: (1) To be in conformance with the new labeling format in § 201.66, and (2) to increase the probability of treatment success based on some of the new information being added to the monograph. The agency is also revising the indications section to the new labeling format in § 201.66.

Several reports have emphasized the importance of combing and environmental control for treatment success and for prevention of reinfestation (Refs. 1 through 5). In 1998, Bainbridge et al. (Ref. 6) reported high clinical efficacy (79/79 treatment successes, defined as no live lice and no nits within 0.25 inches of the scalp, after a second treatment using pyrethrum extract with piperonyl butoxide on day 14 of pediculicide treatment). In the study, the hair was saturated with the pediculicide according to label directions and was thoroughly combed to remove lice and nits. Parents and guardians were provided with instructions regarding treatment of personal contacts and family members of cases, as well as instructed on proper cleaning of the home. Family members were provided with a marketed pediculicide shampoo to use at home to prevent reinfestation of the affected patients if they declined to participate in the study.

Other authors state that thorough combing is necessary to remove lice and eggs that the pediculicide does not kill (Refs. 1, 2, and 5). Because lice removed from the human host can survive up to 2 days and nits can survive away from the host for up to 10 days (Ref. 3), the agency believes that additional information about careful disposal of lice and nits combed out of the hair is very important and useful to consumers.

Other information can also enhance the effectiveness of combing. Lice and nits are small and hard to see; thus, good lighting is essential and magnification is recommended (Refs. 4 and 5). Before hatching, nits are small, whitish-yellow ovals that are found close to the scalp, cemented firmly to the hair shaft (Ref. 4). Nits hatch within 7 to 10 days. Once hatched, the empty, white nit case remains glued to the hair. When searching the hair, other small white objects may be easily seen. If these objects are displaced easily from the hair, they are not nits and are most likely dandruff (Refs. 1, 3, and 4).

Lice are transmitted by actual contact with infested persons, bedding materials, or articles of clothing (Refs. 2 through 5). To prevent reinfestation, environmental measures need to be taken as indicated in § 358.650(c) of the monograph. Clothing, linens, and towels need to be washed in hot water and dried in a hot dryer for at least 20 minutes. Vacuuming of rugs, carpets,

upholstered furniture, and car seats is also recommended. Anything that cannot be laundered or vacuumed should be sealed in a plastic bag for 4 weeks. Personal combs and brushes may be disinfected by soaking in hot water (above 54 °C (130 °F)) for 5 to 10 minutes. As discussed above, the agency believes that it is necessary to inspect and treat family members and personal contacts and to clean or dispose of fomites¹ properly (Refs. 3, 4, and 5). These ancillary measures contributed to the high treatment success rate in the Bainbridge study (Ref. 6). The agency believes that using plain language in informing consumers about the reasons for label recommendations would improve compliance.

A second treatment after 7 to 10 days is essential because the first treatment: (1) May not kill all of the lice, (2) does not have any effect on nits within the first 4 days after the eggs have been laid because the nervous system has not yet developed in the louse embryo (Refs. 1, 4, and 5), and (3) has no residual lice-killing effect after the product is washed out of hair.

B. The Agency's Specific Recommendations

The current monograph statement of identity in § 358.650(a) provides for “pediculicide (lice treatment)” or “lice treatment.” Because the term “pediculicide” is extra wording that is not needed, the agency is proposing to remove it and to limit the statement of identity to “lice treatment.”

The agency is proposing to convert the labeling in § 358.650(c)(1), (c)(2), and (c)(3) to the format required in § 201.66(c), using the subheadings “Do not use,” “Ask a doctor before use if you have,” “When using this product,” and “Stop use and ask a doctor if.” The proposed labeling includes bullets in accord with § 201.66(d)(4). The agency is deleting § 358.650(c)(4) because that section is currently addressed by § 330.1(i)(23) (21 CFR 330.1(i)(23)).

The agency is revising the warning statement “Use with caution on persons allergic to ragweed” in § 358.650(c)(1) to read: “Ask a doctor before use if you are [bullet] allergic to ragweed.

¹ Items such as a book, wooden object, or clothing that is not in itself harmful, but is able to harbor lice or nits and thus may serve as an agent of transmission of an infestation.

May cause breathing difficulty or an asthmatic attack.” This warning would appear in new § 358.650(c)(3).

The current warnings in § 358.650(c)(2) state in part:

* * * Do not use near the eyes or permit contact with mucous membranes, such as inside the nose, mouth, or vagina, as irritation may occur. Keep out of eyes when rinsing hair. Adults and children: Close eyes tightly and do not open eyes until product is rinsed out. Also, protect children’s eyes with washcloth, towel or other suitable material, or by a similar method. * * *

The agency is shortening these warning statements by deleting: (1) “* * * or permit contact with mucous membranes, such as * * *” and “* * * as irritation may occur” from the first sentence, (2) “Adults and children:” from the third sentence, and (3) “Also,” “children’s” and “or other suitable material, or by a similar method” from the fourth sentence. The revised warnings appear under the subheadings “Do not use” (new § 358.650(c)(2)) or “When using this product” (new § 358.650(c)(4)), as follows: “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 [bullet] if product gets in eyes, flush with water right away [bullet] scalp itching or redness may occur.”

The agency is making two minor changes in the last warning statement in current § 358.650(c)(2) that states “If product gets into the eyes, immediately flush with water.” The agency is substituting “in” for “into” and “right away” for “immediately,” and moving “right away” to the end of the warning.

The current warnings in § 358.650(c)(3) state “If skin irritation or infection is present or develops, discontinue use and consult a doctor. Consult a doctor if infestation of eyebrows or eyelashes occurs.” The agency is revising the first sentence and placing it in new § 358.650(c)(5) to read: “Stop use and ask a doctor if [bullet] skin or scalp irritation continues or infection occurs.” The agency is moving the second sentence to under the “Do not use” subheading in new § 358.650(c)(2) to read “[bullet] on lice in eyebrows or eyelashes. See a doctor.”

Table 1 shows how, using the format in § 201.66(c)(5), the agency is revising the warnings in § 358.650(c) of the final monograph in this proposed amendment.

TABLE 1.—REVISION OF FINAL MONOGRAPH WARNINGS TO NEW FORMAT

Pediculicide Final Monograph	Proposed Amendment to Monograph
For external use only.	For external use only. ²
Do not use near the eyes or permit contact with mucous membranes, such as inside the nose, mouth, or vagina, as irritation may occur. Consult a doctor if infestation of eyebrows or eyelashes occurs.	Do not use <ul style="list-style-type: none"> • near eyes • inside nose, mouth, or vagina • on lice in eyebrows or eyelashes. See a doctor.
Use with caution on persons allergic to ragweed.	Ask a doctor before use if you are <ul style="list-style-type: none"> • allergic to ragweed. May cause breathing difficulty or an asthmatic attack.
Keep out of eyes when rinsing hair. Adults and children: Close eyes tightly and do not open eyes until product is rinsed out. Also, protect children's eyes with washcloth, towel or other suitable material, or by a similar method. If product gets into the eyes, immediately flush with water.	When using this product <ul style="list-style-type: none"> • keep eyes tightly closed and protect eyes with a washcloth or towel • if product gets in eyes, flush with water right away • scalp itching or redness may occur
If skin irritation or infection is present or develops, discontinue use and consult a doctor.	Stop use and ask a doctor if <ul style="list-style-type: none"> • breathing difficulty occurs • eye irritation occurs • skin or scalp irritation continues or infection occurs

² In bold type on the line immediately following the line for the Warnings heading. See § 201.66(c)(5)(i) and (d)(6) of this chapter.

The agency is amending the “Directions” in § 358.650(d) to provide greater detail. The directions for all products would include directions for adults and children 2 years and over and direct consumers to ask a doctor for children under 2 years. The directions would include new captions entitled “Treat” and “Remove lice and their eggs (nits)” and information to see a doctor for other treatments if infestation continues. The directions for head lice treatment products would also include a new caption entitled “Inspect.” The proposed labeling includes bullets in accord with § 201.66(d)(4).

The current direction in § 358.650(d)(1) reads: “*For all products. ‘Important: Read warnings before using.’* [statement in boldface type].” The agency is revising this direction by changing “using” to “use,” and requiring this statement to appear first. This statement appears in new § 358.650(d)(1).

The agency is adding a heading in new § 358.650(d)(2) that states: “adults and children 2 years and over:” [in bold type]. The agency has a safety concern that there may be a greater

likelihood of percutaneous absorption of topically applied pediculicide drug products by children under 2 years of age.

The agency is adding new § 358.650(d)(3) for head lice treatment products. This new section adds the following statements: “Inspect [bullet] check each household member with a magnifying glass in bright light for lice/nits (eggs) [bullet] look for tiny nits near scalp, beginning at back of neck and behind ears [bullet] examine small sections of hair at a time [bullet] unlike dandruff which moves when touched, nits stick to the hair [bullet] if either lice or nits are found, treat with this product”.

The agency is moving the information currently in § 358.650(d)(2) and (d)(3) to new § 358.650(d)(4) for manufacturers to select the directions for either shampoo or nonshampoo products. The agency is revising some of the text in the new paragraph and adding the phrases “for head lice, first apply behind ears and to back of neck,” “use warm water to form a lather, shampoo, then thoroughly rinse” for shampoo products; “wash area thoroughly with warm water and soap or shampoo” for nonshampoo products; and “for head lice, towel dry hair and comb out tangles” for both types of products.

The agency is adding new “Remove lice and their eggs (nits)” information for all products in § 358.650(d)(5). This new information adds the following statements:

[bullet] use a fine-tooth or special lice/nit comb. Remove any remaining nits by hand (using a throw-away glove). [bullet] hair should remain slightly damp while removing nits [bullet] if hair dries during combing, dampen slightly with water [bullet] for head lice, part hair into sections. Do one section at a time starting on top of head. Longer hair may take 1 to 2 hours. [bullet] lift a 1 to 2 inch wide strand of hair. Place comb as close to scalp as possible and comb with a firm, even motion away from scalp. [bullet] pin back each strand of hair after combing [bullet] clean comb often. Wipe nits away with tissue and discard in a plastic bag. Seal bag and discard to prevent lice from coming back. [bullet] after combing, thoroughly recheck for lice/nits. Repeat combing if necessary. [bullet] check daily for any lice/nits that you missed.

The agency is proposing new § 358.650(d)(6) and (d)(7) as follows: “[bullet] a second treatment must be done in 7 to 10 days to kill any newly hatched lice [bullet] if infestation continues, see a doctor for other treatments”. Paragraph (d)(6) incorporates information in existing § 358.650(d)(2) and (d)(3).

Table 2 shows how the agency is revising the directions in § 358.650(d) of the final monograph in this proposed amendment.

TABLE 2.—REVISION OF FINAL MONOGRAPH DIRECTIONS TO NEW FORMAT

Pediculicide Final Monograph	Proposed Amendment to Monograph
<p>Important: Read warnings before using.</p> <p>Apply to affected area until all the hair is thoroughly wet with product.</p> <p>Allow product to remain on area for 10 minutes but no longer. Add sufficient warm water to form a lather and shampoo as usual. Rinse thoroughly.</p> <p>Wash area thoroughly with warm water and soap or shampoo.</p> <p>A fine-toothed comb or a special lice/nit removing comb may be used to help remove dead lice or their eggs (nits) from hair.</p> <p>A second treatment must be done in 7 to 10 days to kill any newly hatched lice.</p>	<ul style="list-style-type: none"> • Important: Read warnings before use. • adults and children 2 years and over: <p>Inspect</p> <ul style="list-style-type: none"> • check each household member with a magnifying glass in bright light for lice/nits • look for tiny nits near scalp, beginning at back of neck behind ears • examine small sections of hair at a time • unlike dandruff which moves when touched, nits stick to the hair • if either lice or nits (eggs) are found, treat with this product <p>Treat</p> <ul style="list-style-type: none"> • apply thoroughly to hair or other affected area. For head lice, first apply behind ears and to back of neck. • allow product to remain for 10 minutes, but no longer • use warm water to form a lather, shampoo, then thoroughly rinse³ <ul style="list-style-type: none"> • wash area thoroughly with warm water and soap or shampoo⁴ • for head lice, towel dry hair and comb out tangles⁵ <p>Remove lice and their eggs (nits)</p> <ul style="list-style-type: none"> • use a fine-tooth or special lice/nit comb. Remove any remaining nits by hand (using a throw-away glove). • hair should remain slightly damp while removing nits • if hair dries during combing, dampen slightly with water • for head lice, part hair into sections. Do one section at a time starting on top of head. Longer hair may take 1 to 2 hours. • lift a 1 to 2 inch wide strand of hair. Place comb as close to scalp as possible and comb with a firm, even motion away from scalp. • pin back each strand of hair after combing • clean comb often. Wipe nits away with tissue and discard in a plastic bag. Seal bag and discard to prevent lice from coming back. • after combing, thoroughly recheck for lice/nits. Repeat combing if necessary. • check daily for any lice/nits that you missed • 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 • children under 2 years: ask a doctor.

³ For shampoo products only.

⁴ For nonshampoo products only.

⁵ For shampoo and nonshampoo products.

Current § 358.650(e) describes “other required statements” for these products. The agency is proposing that those statements now appear under the heading “Other information,” in accord with § 201.66(c)(7), and that this information may appear in a package insert. If a package insert is used, the “Other information” section shall include a statement referring to the package insert for

additional information. The agency is retaining the current section titles “Head lice,” “Pubic (crab) lice,” and “Body lice” but requiring that they appear in bold type. The agency is restating the text using the bullet format. In the “Head lice” section, the agency is changing from 2 to 4 weeks the time for dry-cleaning or sealing in a plastic bag items that cannot be washed. The expanded time is being proposed for greater assurance of preventing reinfestation of the same items. In the same section, the agency is adding the statement “[bullet] vacuum all carpets, mattresses, upholstered furniture, and car seats that may have been used by affected people”.

III. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation).

The agency believes that this proposed rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. In accordance with the Executive order, FDA has analyzed the potential economic effects of this proposed rule. FDA has determined, as discussed below, that the proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation. The current inflation adjusted statutory threshold is about \$110 million.

The purpose of this proposed rule is to revise and improve the statement of identity, warnings, directions, and other required labeling statements for OTC pediculicide drug products. The revised labeling provides more detailed information on the proper use of the product and should improve consumers' self-use.

The proposed rule would require relabeling of OTC pediculicide drug products containing pyrethrum extract with piperonyl butoxide. The agency's drug listing system identifies about 23 manufacturers and 36 marketers of approximately 75 stockkeeping units (SKU) (individual products, packages, and sizes) of OTC pediculicide drug products. There may be a few additional marketers and products that are not identified in the sources FDA reviewed.

The agency does not believe that manufacturers would need to increase the package size to add the additional labeling information. Almost all of these products are marketed in an outer carton and should have adequate space for the additional information. Assuming that there are about 75 affected OTC SKUs in the marketplace, FDA estimates (based on information provided by OTC drug manufacturers) that the rule would impose total one-time compliance costs on industry for relabeling of about \$3,000 to \$4,000 per SKU, for a total cost of \$225,000 to \$300,000.

The agency believes the actual cost could be lower for several reasons. First, most of the labeling changes will be made by private label small manufacturers that tend to use simpler and less expensive labeling.

Second, the compliance dates for labeling OTC pediculicide drug products in the new standardized format required by § 201.66 are May 16, 2002, and May 16, 2003 (if annual sales of the product are less than \$25,000). (See the **Federal Register** of June 20, 2000 (65 FR 38191 at 38193).) This proposal alerts manufacturers of these products that additional labeling revisions

will be required in the future. Thus, manufacturers should be able to control the amount of labeling in inventory. In addition, the agency is proposing that any final rule that may issue based on this proposal become effective 18 months after its publication (with a compliance date of 24 months after publication for products with annual sales less than \$25,000). Thus, manufacturers should have ample time to use up the first batch of new labeling that complies with § 201.66, and the labeling changes that result from this proposed rule may be done in the normal course of business.

The final rule will not require any new reporting and recordkeeping activities. Therefore, no additional professional skills are needed. Further, manufacturers will not incur any expenses determining how to state the product's labeling because the proposed amendment (and eventual final rule) provide that information.

The agency considered but rejected several labeling alternatives: (1) A shorter or longer implementation period, and (2) an exemption from coverage for small entities. While the agency believes that consumers would benefit from having this labeling, as proposed, in place as soon as possible, the agency also acknowledges that labeling for these products needs to be converted to the new OTC "Drug Facts" format by May 16, 2002 (May 16, 2003, for products with annual sales less than \$25,000). A final rule based on this proposal will not issue before May 16, 2002, and the agency cannot currently predict exactly when a final rule would issue. The agency believes that 18 months is a reasonable period of time for manufacturers to use up new labeling that is printed to comply with the May 16, 2002, date. The agency rejects an exemption for small entities because the new labeling information is also needed by consumers who purchase products marketed by those entities. However, a longer compliance date (24 months) is being provided for products with annual sales less than \$25,000.

OTC pediculicide drug products are not the sole products produced by manufacturers affected by this rule. The agency believes the incremental costs of this proposed rule will be less than 1 percent of any of the manufacturer's total sales. Therefore, the agency certifies that this proposed

rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required under the Regulatory Flexibility Act (5 U.S.C. 605(b)).

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a “collection of information” under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) Rather, the proposed statement of identity, warnings, directions, and other information are a “public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)).

V. Environmental Impact

The agency has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

VII. Request for Comments

Interested persons may submit written or electronic comments regarding this proposal to the Dockets Management Branch (address above) by *[insert date 90 days after date of publication*

in the Federal Register]. Written comments on the agency's economic impact determination may be submitted on or before [*insert date 90 days after date of publication in the Federal Register*]. Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Proposed Effective Date

The agency is proposing that any final rule that may issue based on this proposal become effective 18 months after its date of publication in the **Federal Register**. The agency is proposing that the compliance date for products with annual sales less than \$25,000 would be 24 months after the date of publication in the **Federal Register**. The compliance date for all other OTC drug products would be 18 months after the date of publication in the **Federal Register**.

IX. References

The following references are on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Elston, D. M., "What's Eating You? Pediculus Humanus (Head Louse and Body Louse)," *Cutis*, 63:259–264, 1999.
2. Burkhart, C. G. et al., "An Assessment of Topical and Oral Prescription and Over-The-Counter Treatments for Head Lice," *Journal of the American Academy of Dermatology*, 38:979–982, 1998.
3. Sokoloff, F., "Identification and Management of Pediculosis," *Nurse Practitioner*, 19:62–64, 1994.
4. Clore, E. R., "Pediculosis Screening and Treatment," *School Nurse*, 6:14–23, 1990.
5. Shaw, K., "Eradicating Head Lice: A Review for Pharmacists," *Pharmacy Times*, 64:48–50, 1998.

6. Bainbridge, C. V. et al., “Comparative Study of the Clinical Effectiveness of a Pyrethrin-Based Pediculicide with Combing Versus a Permethrin-Based Pediculicide with Combing,” *Clinical Pediatrics*, 37:17–22, 1998.

List of Subjects in 21 CFR Part 358

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 358 be amended as follows:

PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 358 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 358.650 is revised to read as follows:

§ 358.650 Labeling of pediculicide drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a “lice treatment.”

(b) *Indications.* The labeling of the product states, under the heading “Uses,” the following: “treats head, pubic (crab), and body lice.” Other truthful and nonmisleading statements, describing only the uses that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings*. The labeling of the product contains the following warnings under the heading “Warnings”:

- (1) “For external use only” in accord with § 201.66 (c)(5)(i) of this chapter.
- (2) “Do not use [bullet]¹ near eyes [bullet] inside nose, mouth, or vagina [bullet] on lice in eyebrows or eyelashes. See a doctor.”
- (3) “Ask a doctor before use if you are [bullet] allergic to ragweed. May cause breathing difficulty or an asthmatic attack.”
- (4) “When using this product [bullet] keep eyes tightly closed and protect eyes with a washcloth or towel [bullet] if product gets in eyes, flush with water right away [bullet] scalp itching or redness may occur”.
- (5) “Stop use and ask a doctor if [bullet] breathing difficulty occurs [bullet] eye irritation occurs [bullet] skin or scalp irritation continues or infection occurs”.

(d) *Directions*. The labeling of the product contains the following information under the heading “Directions”:

- (1) The labeling states “[bullet] Important: Read warnings before use” [statement shall appear first and in bold type].
- (2) The labeling states “adults and children 2 years and over:” [in bold type].
- (3) For head lice treatment products “Inspect [in bold type] [bullet] check each household member with a magnifying glass in bright light for lice/nits (eggs) [bullet] look for tiny nits near scalp, beginning at back of neck and behind ears [bullet] examine small sections of hair at a time [bullet] unlike dandruff which moves when touched, nits stick to the hair [bullet] if either lice or nits are found, treat with this product”.
- (4) Select one of the following:
 - (i) *For shampoo products* “Treat [in bold type] [bullet] apply thoroughly to hair or other affected area. For head lice, first apply behind ears and to back of neck. [bullet] allow product

¹See § 201.66(b)(4) of this chapter for definition of bullet symbol.

to remain for 10 minutes, but no longer [bullet] use warm water to form a lather, shampoo, then thoroughly rinse [bullet] for head lice, towel dry hair and comb out tangles”.

(ii) *For nonshampoo products* “Treat [in bold type] [bullet] apply thoroughly to hair or other affected area. For head lice, first apply behind ears and to back of neck. [bullet] allow product to remain for 10 minutes, but no longer [bullet] wash area thoroughly with warm water and soap or shampoo [bullet] for head lice, towel dry hair and comb out tangles”.

(5) “Remove lice and their eggs (nits) [in bold type] [bullet] use a fine-tooth or special lice/nit comb. Remove any remaining nits by hand (using a throw-away glove). [bullet] hair should remain slightly damp while removing nits [bullet] if hair dries during combing, dampen slightly with water [bullet] for head lice, part hair into sections. Do one section at a time starting on top of head. Longer hair may take 1 to 2 hours. [bullet] lift a 1 to 2 inch wide strand of hair. Place comb as close to scalp as possible and comb with a firm, even motion away from scalp. [bullet] pin back each strand of hair after combing [bullet] clean comb often. Wipe nits away with tissue and discard in a plastic bag. Seal bag and discard to prevent lice from coming back. [bullet] after combing, thoroughly recheck for lice/nits. Repeat combing if necessary. [bullet] check daily for any lice/nits that you missed”.

(6) The labeling states “[bullet] a second treatment must be done in 7 to 10 days to kill any newly hatched lice”.

(7) The labeling states “[bullet] if infestation continues, see a doctor for other treatments”.

(8) The labeling states “children under 2 years:” [in bold type] “ask a doctor”.

(e) The labeling of the product contains the following statements, as appropriate, under the heading “Other information.” This information may appear in a package insert. If a package insert is used, the “Other information” section shall include a statement referring to the package insert for additional information.

(1) “Head lice [highlighted in bold type] [bullet] lay small white eggs (nits) on hair shaft close to scalp [bullet] nits are most easily found on back of neck or behind ears [bullet] disinfect

hats, hair ribbons, scarves, coats, towels, and bed linens by machine washing in hot water (above 54 °C (130 °F)), then using hottest dryer cycle for at least 20 minutes [bullet] items that cannot be washed (bedspreads, blankets, pillows, stuffed toys, etc.) should be dry-cleaned or sealed in a plastic bag for 4 weeks, then removed outdoors and shaken out very hard before using again [bullet] items that cannot be washed, dry-cleaned, or stored may be sprayed with a product designed for this purpose [bullet] soak all combs and brushes in hot water (above 54 °C (130 °F)) for at least 10 minutes [bullet] vacuum all carpets, mattresses, upholstered furniture, and car seats that may have been used by affected people”.

(2) “**Pubic (crab) lice** [bullet] may be transmitted by sexual contact. Sexual partners should be treated simultaneously to avoid reinfestation [bullet] lice are very small and look like brown or grey dots on skin [bullet] usually cause intense itching and lay small white eggs (nits) on the hair shaft generally close to the skin surface [bullet] may be present on the short hairs of groin, thighs, trunk, and underarms, and occasionally on the beard and mustache [bullet] disinfect underwear by machine washing in hot water (above 54 °C (130 °F)), then using hottest dryer cycle for at least 20 minutes”.

(3) “**Body lice** [bullet] body lice and their eggs (nits) are generally found in the seams of clothing particularly in waistline and armpit area [bullet] body lice feed

on skin then return to clothing to lay their eggs [bullet] disinfect clothing by machine washing in hot water (above 54 °C (130 °F)), then using hottest dryer cycle for at least 20 minutes [bullet] do not seal clothing in a plastic bag because nits can remain dormant for up to 30 days”.

Dated: _____

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