DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 358

[Docket No. 81N–0201]

RIN 0905–AA06

Pediculicide Drug Products for Over-The-Counter Human Use; Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph establishingconditions under which over-the-counter (OTC) pediculicide drug products (products used for the treatment of head, pubic (crab), and body lice) are generally recognized as safe and effective and not misbranded. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on pediculicide drug products that have come to the agency's attention. This final monograph is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Effective on June 14, 1994, for § 310.545 (21 CFR 310.545); and effective on December 14, 1994, for part 358, subpart G (21 CFR part 358, subpart G).

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 29, 1982 (47 FR 28312), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC pediculicide drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by September 27, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by October 27, 1982.

In accordance with § 330.10(a)(10), the data and information considered by the Panel, after deletion of a small amount of trade secret information, were placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

The agency's proposed regulation, in the form of a tentative final monograph, for OTC pediculicide drug products was published in the **Federal Register** of April 3, 1989 (54 FR 13480). Interested persons were invited to file by June 2, 1989, written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs (the Commissioner) regarding the proposal. Interested persons were invited to file comments on the agency's economic impact determination by August 1, 1989. New data could have been submitted until April 3, 1990, and comments on the new data could have been submitted until June 4, 1990. Final agency action occurs with the publication of this final monograph, which is a final rule establishing a monograph for OTC pediculicide drug products.

The OTC drug procedural regulations (§ 330.10) provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA is no longer using the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but is using instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III).

As discussed in the proposed regulation for OTC pediculicide drug products (54 FR 13480), the agency advised that the conditions under which the drug products that are subject to this monograph will be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication in the **Federal Register**. Therefore, on or after December 14, 1994, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In response to the proposed rule on OTC pediculicide drug products, two drug manufacturers submitted comments, one of which included a request for an oral hearing before the Commissioner on three different issues. A copy of the comments received is on public display in the Dockets Management Branch (address above). Additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

I. The Agency's Conclusions on The Comments

A. Comment on Ingredients

1. One comment requested a hearing to clarify: (1) The composition and concentration of constituents of pyrethrum extract, (2) current pyrethrum flower extraction and extract refining methods, and (3) methods and protocols for establishing appropriate standards for pyrethrum extract. The comment mentioned that the chemistry of pyrethrins and pyrethrum extracts was currently under review by the U.S. Environmental Protection Agency (EPA) as part of its reregistration procedures.

The agency denied the comment's request for a hearing on July 24, 1989 (Ref. 1). The agency stated that, at the time the hearing request was made, reasonable grounds did not exist to support granting the request, because there was insufficient information on these three subjects in the administrative record for resolution at a hearing. Information subsequently made available to FDA resolved these issues.

The agency contacted EPA to obtain information on the chemical identity or pyrethrum extract, and EPA referred FDA to two sources of information. One source (Ref. 2) stated that pyrethrum dried flowers contain 0.9 to 1.3 percent pyrethrins, but did not provide a breakdown of other components. The second source (Ref. 3) included a table of the composition of the pyrethrins in what it referred to as a typical

pyrethrum oleoresin. It grouped pyrethrins I as 14.8 percent with a breakdown of cinerin I at 2.2 percent, jasmolin I at 1.2 percent, and pyrethrin I at 11.4 percent (Ref. 3). It also grouped pyrethrins II as 15.2 percent with a breakdown of cinerin II at 3.5 percent, jasmolin II at 1.2 percent, and pyrethrin II at 10.5 percent (Ref. 3). The agency verified those amounts from another source (Ref. 4), but could not determine whether those amounts represent the composition of components in pyrethrum extract as currently obtained and could not determine what is meant by a "typical" oleoresin.

Other information on the chemical composition and concentration of pyrethrum extract constituents was subsequently provided to the agency (Ref. 5), and a monograph in the United States Pharmacopeia (U.S.P.) has now been developed for this ingredient (Ref. 6). The U.S.P. monograph identifies the ingredient as pyrethrum extract instead of pyrethrins and provides a current standard for the chemical constituency of pyrethrum extract. Both the U.S.P. and EPA (Ref. 7) agree that the ratio of Pyrethrins I to Pyrethrins II in the extract is in a range of 0.8 to 2.8, and FDA finds this range to be acceptable. Based on these subsequent events, the agency sees no need for a hearing on these issues.

References

(1) Letter from W. E. Gilbertson, FDA, to W. Gullickson, McLaughlin Gormley King Co., coded LET011, Docket No. 81N–0201, Dockets Management Branch.

(2) Farm Chemicals Handbook '92, Pesticide Dictionary, Pyrethrum, Meister Publishing Co., Willoughby, OH, p. C283.

(3) Head, S. W., "Composition of Pyrethrum Extract and Analysis of Pyrethrins," in "Pyrethrum The Natural Insecticide," edited by J. E. Casida, Academic Press, New York, p. 30, 1973.

(4) Head, S. W., "The Composition of Pyrethrum Extract," Pyrethrum Post, 10(2): 17–21, 1969.

(5) Letters from the Nonprescription Drug Manufacturers Association to The U.S. Pharmacopeial Convention, Inc., coded LET12, LET13, and LET14, Docket No. 81N–0201, Dockets Management Branch.

(6) "The United States Pharmacopeia XXII and The National Formulary XVII," 8th Supp., The U.S. Pharmacopeial Convention, Inc., Rockville, MD, p. 3300, March 1993.

(7) Letter from J. W. Akerman, EPA, to R. Engel, Chemical Specialties Manufacturers Association., OTC vol. 16KFM, Docket No. 81N–0201, Dockets Management Branch, October 1, 1986.

B. Comments on Labeling

2. One comment suggested an addition to the second sentence of the proposed warning in § 358.650(c)(2), which states: "Do not use near the eyes or permit contact with mucous membranes." The comment mentioned the possibility that, despite the warning, a physician may suggest use of the product to treat an infestation of the eyebrows and eyelashes. The comment stated that there is no explanation as to why the product should not be used near the eyes, and an explanation would be appropriate. The comment suggested the following: "Do not use near the eyes or permit contact with mucous membranes as it may cause irritation."

The agency agrees with the comment that an explanation would be beneficial to consumers. In its report on OTC pediculicide drug products, the Panel discussed a number of studies that showed pyrethrins and piperonyl butoxide are irritating to the eyes and mucous membranes (47 FR 28312 at 28316 and 28317). The American Medical Association reports that commercial formulations of pyrethrins and piperonyl butoxide are irritating to the eyes and mucous membranes and should not be used to treat infestations of the eyelashes (Ref. 1). In discussing the proper use of pyrethrins with piperonyl butoxide, USPDI (Ref. 2) instructs the user to "Keep this medicine away from the eyes and other mucous membranes, such as inside the nose, because it may cause irritation." The agency believes that the warning would be more beneficial to consumers by also specifying the location of mucous membranes near the eyes. Accordingly, the agency is revising the second sentence of the proposed warning in § 358.650(c)(2) to read "Do not use near the eyes or permit contact with mucous membranes, such as inside the nose, mouth, or vagina, as irritation may occur."

References

(1) Drug Evaluations Subscription, vol. III, Topical Drugs Used in Ear, Skin, and Mucous Membrane Infections, Pediculosis, American Medical Association, Chicago, pp. 2:31–2:35, Spring 1990.

(2) USPDI, vol. II, 13th ed., Advice for the Patient, Drug Information in Lay Language, Pyrethrins and Piperonyl Butoxide (Topical), The U.S. Pharmacopeial Convention, Inc., Rockville, MD, p. 1082, 1992.

3. One comment suggested that the directions provide for a "special lice/nit removing comb" instead of a "fine-toothed comb." The comment contended that a fine-toothed comb may not always be effective in removing nits from hair.

The agency agrees that the directions could provide for the use of a "special lice/nit removing comb," but not to the exclusion of a "fine-toothed comb." The Panel stated that "Dead and empty nits will remain attached to the hairs and be unsightly as well as confusing to those who cannot distinguish between live and dead nits; therefore, it may be desirable to remove them by combing with a fine-toothed comb," (47 FR 28312 at 28315). If a fine-toothed comb should not be effective in removing nits from hair, the consumer is alerted to the existence of the "special lice/nit removing comb," which may be used alternatively. Therefore, in this final monograph, § 358.650(d)(2) and (d)(3) are revised to mention use of either type of comb.

4. One comment requested that the "Other required statements" in § 358.650(e) regarding head, pubic (crab), and body lice, as well as other relevant patient instructions such as the proper use of a lice/nit removing comb, be allowed to appear in a package insert or booklet. The comment contended that the required statements are too verbose for inclusion on the product label or outer carton labeling.

The agency has no objection to the request. A package insert or booklet containing the "Other required statements" would be fully acceptable, provided it is referred to on the product label or outer carton labeling. The referencing statement should alert consumers to read the package insert or booklet before using the product and to save the information for future use or reference.

II. Summary of Significant Changes From The Proposed Rule

1. The active ingredient pyrethrins is now identified as pyrethrum extract. (See comment 1.) Accordingly, § 358.610 has been revised to read: "The active ingredients of the productconsist of the combination of pyrethrum extract (0.17 to 0.33 percent) with piperonyl butoxide (2 to 4 percent) in a nonaerosol dosage formulation."

The agency is aware that the U.S. Pharmacopoeial Convention, Inc., is currently developing a compendial monograph for piperonyl butoxide. Following development of that monograph, the agency will revise § 358.610 as necessary, for example, to accommodate changes in nomenclature.

2. The directions in § 358.650(d)(2) and (d)(3) have been revised to provide for the use of either a special lice/nit removing comb or a fine-toothed comb to help remove dead lice or nits from hair. (See comment 3.)

3. The agency has reviewed reports of adverse reactions for pyrethrin-containing drug products in its Spontaneous Reporting System. From 1979 through February 1993, 45 reports were received (Ref. 1). Of those 45 reports, 40 involved ocular toxicity

(including corneal lesions, keratitis, uveitis, and conjunctivitis) and 18 of these involved children under 10 years of age whose hair was washed with the medication (a shampoo formulation) by another person. Based on these reports, the agency is concerned that significant numbers of persons who apply the product on themselves or on young children do not read the label warning to avoid contact of the product with the eyes or do not exercise sufficient care to keep the product out of the eyes.

Accordingly, the agency is expanding the warning in § 358.650(c)(2) of this final monograph to include additional clarifying information as follows:

For external use only. 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. If product gets into the eyes, immediately flush with water.

To better bring this and other warnings to the consumer's attention, the agency is adding a new direction to state: "Important: Read warnings before using." Because of the importance of these warnings, the agency is requiring that this directions statement about reading the warnings appear in all capital letters and in boldface type. The new statement on protecting eyes and mucous membranes is being included separately in § 358.650(d)(1) of the final monograph because it applies to all products. With the addition of the new statement, proposed § § 358.650(d)(1) and (d)(2) are redesignated as § § 358.650(d)(2) and (d)(3), respectively, in this final monograph.

Reference

(1) FDA Spontaneous Reporting System, Computer Printout of Adverse Reactions Reported for Pyrethrin-Containing Drug Products, in OTC vol. 16KFM, Docket No. 81N–0201, Dockets Management Branch, February 26, 1993.

4. The warning statement "Consult a doctor if infestation of eyebrows or eyelashes occurs," previously included as part of § 358.650(c)(2) in the tentative final monograph, has been incorporated with the warning in § 350.650(c)(3) of this final monograph, to read:

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.

III. The Agency's Final Conclusions on OTC Pediculicide Drug Products

Based on available evidence, the agency is issuing a final monongraph establishing conditions under which OTC pediculicide drug products are generally recognized as safe and effective and not misbranded. Specifically, the agency has determined that the only ingredient that meets monograph conditions is the combination of pyrethrum extract and piperonyl butoxide. All other ingredients considered in this rulemaking have been determined to be nonmonograph for use in a pediculicide drug product. These ingredients include, but are not limited to, benzocaine, benzyl alcohol, benzyl benzoate, chlorophenothane (dichlorodiphenyl trichloroethane), aqueous coconut oil soap, copper oleate, docusate sodium, formic acid, isobornyl thiocyanoacetate, picrotoxin, propylene glycol, sabadilla alkaloids, sublimed sulfur, and thiocyanoacetate.

The agency has established 21 CFR 310.545 in which are listed certain active ingredients that are not generally recognized as safe and effective for certain OTC drug uses. That final rule included in § 310.545(a)(25) the 14 nonmonograph pediculicide active ingredients listed above, with an effective date of November 10, 1993. The agency is redesignating § 310.545(a)(25) as § 310.545(a)(25)(i), and is adding § 310.545(a)(25)(ii) to include the nonmonograph pediculicide active ingredient pyrethrum extract (formerly named pyrethrins) with piperonyl butoxide in an aerosol dosage form. This entity was classified in Category III in the summary of ingredient categories in the tentative final monograph (54 FR 13480 at 13485). The effective date for § 310.545(a)(25)(ii) is on June 14, 1994.

Accordingly, any drug product labeled, represented, or promoted for use as an OTC pediculicide that contains any of the ingredients listed § 310.545(a)(25)(i) or (a)(25)(ii) or that is not in conformance with the monograph (21 CFR part 358, subpart G) may be considered a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S C. 321(p)) and misbranded under section 502 of the act (21 U.S.C. 352) and cannot be marketed for this use unless it is the subject of an approved application under section 505 of the act (21 U.S.C. 355) and part 314 of the regulations (21 CFR part 314). An appropriate citizen petition to amend the monograph may also be submitted under § 10.30 (21 CFR 10.30) in lieu of an application. Any OTC pediculicide drug product initially introduced or initially delivered for introduction into interstate commerce after the effective dates listed above that is not in compliance with the regulations is subject to regulatory action. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (54 FR 13480 at 13487). The agency has examined the economic consequences of this final rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12866, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354). This rulemaking for OTC pediculicide drug products is not expected to have an impact on small businesses. This final rule may require reformulation of a few products. Products that currently contain the allowed active ingredients in nonmonograph concentrations will need to be reformulated to meet the conditions of § 358.610 of this final monograph. Manufacturers will have 1 year to implement changes in compliance with the monograph and may reformulate to monograph conditions without the cost of any clinical testing. If reformulation is necessary, the cost of doing so will vary among manufacturers based on the reformulation choice selected and the costs related to product specific stability testing and other standard manufacturing procedures. The agency believes that the majority of the OTC pediculicide drug products currently marketed already contain the combination of pyrethrum extract and piperonyl butoxide in monograph concentration ranges in a nonaerosol dosage form. These products will need some relabeling. However, the labeling in this final rule is quite similar to that proposed in the tentative final monograph. Based on information provided by a nonprescription drug manufacturers' association, the estimated average cost of a labeling revision is about $2,000 per product label. Products containing pediculicide active ingredients listed in § 310.545(a)(25)(i) have already been covered by a final rule published on May 10, 1993 (58 FR 27636). Therefore, the agency concludes that the final rule is not a major rule as defined in Executive Order 12866. Further, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities

as defined in the Regulatory Flexibility Act.

The agency has determined under 21 CFR 25.24(c)(6) 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.

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

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, 21 CFR parts 310 and 358 are amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

2. Section 310.545 is amended by redesignating the text of paragraph (a)(25) as paragraph (a)(25)(i), by adding new (a)(25)(i) heading and paragraphs (a)(25)(ii) and (d)(16), and by revising paragraph (d) introductory text and paragraph (d)(11) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(25) *Pediculicide drug products*—(i) *Approved as of November 10, 1993.*

* * *

(ii) *Approved as of June 14, 1994. The combination of pyrethrum extract (formerly named pyrethrins) and piperonyl butoxide in an aerosol dosage formulation.*

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(d) Any OTC drug product that is not in compliance withthis section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(22) of this section.

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(11) November 10, 1993, for products subject to paragraph (a)(8)(ii), (a)(10)(v) through (a)(10)(vii), (a)(18)(ii) through (a)(18)(vi), (a)(22)(ii), and (a)(23) through (a)(25)(i) of this section.

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(16) June 14, 1994, for products subject to paragraph (a)(25)(ii) of this section.

Part 358—Miscellaneous External Drug Products For Over-The-Counter Human Use

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

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

4. New subpart G, consisting of §§ 358.601 through 358.650, is added to read as follows:

Subpart G—Pediculicide Drug Products

Sec.
358.601 Scope.
358.603 Definition.
358.610 Pediculicide active ingredients.
358.650 Labeling of pediculicide drug products.

Subpart G—Pediculicide Drug Products

§ 358.601 Scope.

(a) An over-the-counter pediculicide drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of Title 21 unless otherwise noted.

§ 358.603 Definition.

As used in this subpart:

Pediculicide drug product. A drug product for the treatment of head, pubic (crab), and body lice.

§ 358.610 Pediculicide active ingredients.

The active ingredients of the product consist of the combination of pyrethrum extract (0.17 to 0.33 percent) with piperonyl butoxide (2 to 4 percent) in a nonaerosol dosage formulation.

§ 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 "pediculicide (lice treatment)" or "lice treatment."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "For the treatment of head, pubic (crab), and body lice." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, 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) "Use with caution on persons allergic to ragweed."

(2) "For external use only. 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. If product gets into the eyes, immediately flush with water."

(3) "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."

(4) The word "physician" may be substituted for the word "doctor" in any of the warning statements in this paragraph.

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

(1) *For all products.* "Important: Read warnings before using." [sentence in all capital letters and boldface type]

(2) *For nonshampoo products.* "Apply to affected area until all the hair is thoroughly wet with product. Allow product to remain on area for 10 minutes but no longer. Wash area thoroughly with warm water and soap or shampoo. 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. A second treatment must be done in 7 to 10 days to kill any newly hatched lice."

(3) *For products formulated for use as a shampoo.* "Apply to affected area until all the hair is thoroughly wet with product. 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. 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. A second treatment must be done in 7 to 10 days to kill any newly hatched lice."

(e) *Other required statements.*

(1) "*Head Lice*: Head lice live on the scalp and lay small white eggs (nits) on the hair shaft close to the scalp. The nits are most easily found on the nape of the neck or behind the ears. All personal headgear, scarfs, coats, and bed linen should be disinfected by machine washing in hot water and drying, using the hot cycle of a dryer for at least 20 minutes. Personal articles of clothing or bedding that cannot be washed may be dry-cleaned, sealed in a plastic bag for a period of about 2 weeks, or sprayed with a product specifically designed for this purpose. Personal combs and brushes may be disinfected by soaking in hot water (above 130 °F) for 5 to 10 minutes. Thorough vacuuming of rooms inhabited by infected patients is recommended."

(2) "*Pubic (Crab) Lice*: Pubic lice may be transmitted by sexual contact; therefore, sexual partners should be treated simultaneously to avoid reinfestation. The lice are very small and look almost like brown or grey dots on the skin. Pubic lice usually cause intense itching and lay small white eggs (nits) on the hair shaft generally close to the skin surface. In hairy individuals, pubic lice may be present on the short hairs of the thighs and trunk, underarms, and occasionally on the beard and mustache. Underwear should be disinfected by machine washing in hot water; then drying, using the hot cycle for at least 20 minutes."

(3) "*Body Lice*: Body lice and their eggs are generally found in the seams of clothing, particularly in the waistline and armpit area. They move to the skin to feed, then return to the seams of the clothing where they lay their eggs. Clothing worn and not laundered before treatment should be disinfected by the same procedure as described for head lice, except that sealing clothing in a plastic bag is not recommended for body lice because the nits (eggs) from these lice can remain dormant for a period of up to 30 days."

Dated: October 29, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

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