(1) Remove all paint around both rivets, exposing an area of approximately ¾″ in diameter, at the inboard trim tab on top and bottom of each blade (4 places per blade). Use 180 grit or finer abrasive paper, followed by 600 grit or finer paper to eliminate course sanding marks. Sand only in a spanwise direction. Do not use chemical paint strippers.

(2) Inspect the blade skin around the rivets on the upper and lower surfaces (4 locations) using a dye penetrant method.

Note 2: Chordwise cracks in the paint up to 2 inches long which are located along either inboard or outboard edge of the trim tab are acceptable.

(b) Clean the sanded areas prepared in accordance with paragraph (a) of this AD with 111-Trichloroethane or methyl ethyl ketone (MEK) and then apply clear lacquer to seal the unpainted areas.

Note 3: Do not bend the inboard main rotor blade tabs from their present position or utilize them for any subsequent blade tracking adjustment.

(c) Thereafter, prior to the first flight of each day, or at intervals not to exceed 5 hours TIS, whichever occurs first, using a 5-power or higher magnifying glass, visually inspect the upper and lower blade skin surfaces around the inboard trim tab rivets (4 locations) for cracks.

(d) If a crack is found, replace the main rotor blade with an airworthy main rotor blade before further flight.

(e) Installation of a set of main rotor blades, P/N C016–2, constitutes terminating action for the requirements of this AD.

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Los Angeles Aircraft Certification Office.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles Aircraft Certification Office.

(g) Special flight permits will not be issued.

Note 5: Robinson Helicopter Company R44 Service Bulletin SB–27A, revised May 29, 1998, pertains to the subject of this AD.

(h) This amendment becomes effective on August 28, 1998, to all persons except those persons to whom it was made immediately effective by Priority Letter AD 98–12–19, issued June 2, 1998, which contained the requirements of this amendment.

Issued in Fort Worth, Texas, on August 5, 1998.

Henry A. Armstrong,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 98–21706 Filed 8–12–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 358

[Docket No. 81N–0201]

RIN 0910–AA01

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation that established conditions 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. This final rule clarifies that the pediculicide active ingredient, pyrethrum extract, is to provide a specified concentration range of pyrethrins in a formulated product. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: September 14, 1998.

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, 301–827–2245.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 14, 1993 (58 FR 65452), FDA issued a final monograph for OTC pediculicide drug products (part 358 (21 CFR part 358, subpart G)) establishing conditions under which the drug products that are subject to that monograph will be generally recognized as safe and effective and not misbranded. The effective date of that monograph was December 14, 1994. The active ingredients under § 358.610 of the monograph were described as the combination of pyrethrum extract (0.17 to 0.33 percent) with piperonyl butoxide (2 to 4 percent) in a nonaerosol dosage formulation.

On October 30, 1996, the Nonprescription Drug Manufacturers Association (NDMA) requested a technical amendment of the final monograph to clarify that pyrethrum extract in § 358.610 provides a concentration of 0.17 to 0.33 percent pyrethrins in the final product formulation (Ref. 1). NDMA stated that proposed § 358.610 of the tentative final monograph for OTC pediculicide drug products listed ''pyrethrins (0.17 to 0.33 percent)'' as the active ingredient (54 FR 13480 at 13487, April 3, 1989), and that there was no United States Pharmacopeia (USP) monograph for pyrethrins at that time. NDMA noted that a USP monograph entitled ''pyrethrum extract'' (Ref. 2) was in effect at the time of publication of the final monograph for OTC pediculicide drug products in 1993, and FDA used ''pyrethrum extract (0.17 to 0.33 percent)'' in § 358.610. The USP monograph (Ref. 2) stated that pyrethrum extract contains approximately 50 percent of the sum of Pyrethrins I and II. NDMA added that, subsequently, USP changed the concentration of Pyrethrins I and II in pyrethrum extract from 50 percent to 20 percent (Ref. 3). NDMA pointed out that a manufacturer following § 358.610 of the final monograph and the latest USP monograph for pyrethrum extract could produce a product containing one-fifth the desired concentration of pyrethrins. NDMA recommended that the agency publish a technical amendment to revise § 358.610 to state ''* * * pyrethrum extract (providing a concentration of pyrethrins of 0.17 to 0.33 percent) * * *'' instead of ''* * * pyrethrum extract (0.17 to 0.33 percent) * * *.'' NDMA indicated that this amendment would allow manufacturers flexibility in using pyrethrum extract containing either 50 or 20 percent pyrethrins to produce a pediculicide product with the desired concentration of pyrethrins.

II. Description of the Technical Amendment

The agency concurs that amendment of § 358.610 is appropriate and is revising this section accordingly.

Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553). This final rule institutes a change that is nonsubstantive in nature. The change does not alter the required range of pyrethrins for pediculicide active ingredients, but simply clarifies that the range was intended to apply to the pyrethrins in the active ingredients. Therefore, FDA finds that the notice and comment procedures are unnecessary and not in the public interest (5 U.S.C. 553(b) and (d)).

III. References

The following references are on display in the Dockets Management Branch (HFA–305), Food and Drug

Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. LET19, Docket No. 81N090201, Dockets Management Branch.

2. *United States Pharmacopeia 23—National Formulary 18*, United States Pharmacopeial Convention, Inc., Rockville, MD, p. 1345, 1994.

3. *Second Supplement to USP 23 and to NF 18*, United States Pharmacopeial Convention, Inc., Rockville, MD, p. 2671, 1995.

IV. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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 a rule on small entities. This final rule makes a minor clarification in the concentration of an active ingredient. It does not change the manner in which manufacturers make these pediculicide drug products and will not cause any burden on small entities. The agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. This economic analysis, together with other relevant sections of this document, serves as the agency's final regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

The Unfunded Mandates Act (2 U.S.C. 1501 *et seq*.) does not apply to this final rule because it would not 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.

V. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that is categorically excluded from the preparation of an environmental assessment because these actions, as a class, will not result in the production or distribution of any substance and therefore will not result in the production of any substance into the environment.

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, 21 CFR part 358 is 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 358.610 is revised to read as follows:

§ 358.610 Pediculicide active ingredients.

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

Dated: August 5, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–21794 Filed 8–12–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

Income Tax; Taxable Years Beginning After December 31, 1953

CFR Correction

In Title 26 of the Code of Federal Regulations, part 1 (§§ 1.401 to 1.440), revised as of April 1, 1998, in § 1.402(a)–1, paragraphs (b)(2)(ii)(*d*) and (c) were inadvertently omitted. The reinstated text of these paragraphs and the source note read as follows:

§ 1.402(a)–1 Taxability of beneficiary under a trust which meets the requirements of section 401(a).

* * * * *

(b)* * *

(2)* * *

(ii)* * *

(*d*)(*1*) In all other cases, there shall be used the average cost (or other basis) to the trust of all securities of the employer corporation of the type distributed to the distributee which the trust has on hand at the time of the distribution, or which the trust had on hand on a specified inventory date which date does not precede the date of distribution by more than twelve calendar months. If a distribution includes securities of the employer corporation of more than one type, the average cost (or other basis) to the trust of each type of security distributed shall be determined. The average cost to the trust of securities of the employer corporation on hand on a specified inventory date (or on hand at the time of distribution) shall be computed on the basis of their actual cost, considering the securities most recently purchased to be those on hand, or by means of a moving average calculated by subtracting from the total cost of securities on hand immediately preceding a particular sale or distribution an amount computed by multiplying the number of securities sold or distributed by the average cost of all securities on hand preceding such sale or distribution.

(*2*) These methods of computing average cost may be illustrated by the following examples:

Example (*1*). A, a distributee who makes his income tax returns on the basis of a calendar year, receives on August 1, 1954, in a total distribution, to which paragraph (a)(6) of this section is applicable, ten shares of class D stock of the employer corporation. On July 1, 1954 (the specified inventory date of the trust), the trust had on hand 80 shares of class D stock. The average cost of the 10 shares distributed, on the basis of the actual cost method, is $100 computed as follows:

Shares	Purchase date	Cost per share	Total cost
20	June 24, 1954.	$101	$2,020
40	Jan. 10, 1953	102	4,080
20	Oct. 20, 1952	95	1,900
80	.....	8,000	

Example (*2*). B, a distributee who makes his income tax returns on the basis of a calendar year, receives on October 31, 1954, in a total distribution, to which paragraph (a)(6) of this section is applicable, 20 shares of class E stock of the employer corporation. The specified inventory date of the trust is the last day of each calendar year. The trust had on hand on December 31, 1952, 1,000 shares of class E stock of the employer corporation. During the calendar year 1953 the trust distributed to four distributees a total of 100 shares of such stock and acquired, through a number of purchases, a total of 120 shares. The average cost of the