The agency has examined the economic consequences of this final rule and 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 final rule provides alternative labeling options that can be implemented at very little cost by manufacturers at the next printing of labels, for those products for which the manufacturer chooses to make a change. Thus, the rule will have no significant economic impact. The agency concludes that the final rule is not a major rule as defined in Executive Order 12866. Further, the agency certifies that the 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 in 21 CFR Part 330

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 330 is amended as follows:

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

1. The authority citation for 21 CFR part 330 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).

2. Section 330.1 is amended by adding new paragraph (i) to read as follows:

§ 330.1 General conditions for general recognition as safe, effective and not misbranded.

* * * * *

(i) The following terms may be used interchangeably in any of the labeling established in parts 331 through 358 of this chapter:

(1) "Ask" or "consult".
(2) "Assistance" or "help".
(3) "Clean" or "cleanse".
(4) "Continue" or "persist".
(5) "Continues" or "persists".
(6) "Doctor" or "physician".
(7) "Indication" or "use".
(8) "Indications" or "uses".
(9) "Lung" or "pulmonary".

* * * * *

Dated: October 15, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–1791 Filed 1–27–94; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 358

[Docket No. 82N–0214]

RIN 0905–AA06

Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products for Over-the-Counter Human Use; Amendment to the Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the final monograph for over-the-counter (OTC) dandruff, seborrheic dermatitis, and psoriasis drug products to include 0.6 percent micronized selenium sulfide for the control of dandruff. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: January 30, 1995.

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 December 4, 1991 (56 FR 63554), FDA issued a final monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products in subpart H of part 358 (21 CFR part 358, subpart H). The monograph lists selenium sulfide 1 percent in § 358.710(a)(5) as an active ingredient that is used for the control of dandruff. The selenium sulfide included in the monograph is not micronized (reduced to a fine particle size).

In the **Federal Register** of April 5, 1993 (58 FR 17554), the agency published a notice of proposed rulemaking to amend the final monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products to include 0.6 percent micronized selenium sulfide in § 358.710(a) as an active ingredient for the control of dandruff. The agency also proposed to add the following definition for micronized selenium sulfide in § 358.703(e): "Selenium sulfide that has been finely ground and that has a median particle size of approximately 5 micrometers (μm), with not more than 0.1 percent of the particles greater than 15 μm and not more than 0.1 percent of the particles less than 0.5 μm." Interested persons were invited to submit written comments and comments on the agency's economic impact determination by June 4, 1993.

No comments were received in response to the proposed amendment. As discussed in the proposal (58 FR 17554 at 17556), the agency advised that any final rule resulting from this proposed rule would be effective 12 months after its date of publication in the **Federal Register**. Therefore, on or after January 30, 1995, any OTC drug product that is not in compliance with this amendment to the final rule may not be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application or abbreviated application. Further, any OTC drug product subject to the rule that is repackaged or relabeled after the effective date of the rule must be in compliance with the rule regardless of the date that the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the rule at the earliest possible date.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (58 FR 17554 at 17557). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12866. The agency therefore concludes that no one of these rules, including this amendment of the final monograph for OTC dandruff, seborrheic dermatitis, and psoriasis drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an

individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC dandruff, seborrheic dermatitis, and psoriasis drug products is not expected to pose such an impact on small businesses. This final rule will not remove any existing products from the market or require any reformulation or relabeling of existing products. The final rule will increase the scope of active ingredients available to industry for this class of OTC drug products. This final rule would allow OTC drug products containing 0.6 percent micronized selenium sulfide and labeled for the control of dandruff to be marketed without having to obtain an approved application, as is currently required. This will be beneficial to small manufacturers. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

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 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: 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).

2. Section 358.703 is amended by adding paragraph (e) to read as follows:

§ 358.703 Definitions.

* * * * *

(e) Selenium sulfide, micronized. Selenium sulfide that has been finely ground and that has a median particle size of approximately 5 micrometers (μm), with not more than 0.1 percent of the particles greater than 15 μm and not more than 0.1 percent of the particles less than 0.5 μm.

3. Section 358.710 is amended by redesignating paragraph (a)(6) as paragraph (a)(7) and by adding new paragraph (a)(6) to read as follows:

§ 358.710 Active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis.

* * * * *

(a) * * *

(6) Selenium sulfide, micronized, 0.6 percent.

* * * * *

Dated: August 26, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–1789 Filed 1–27–94; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IL 35–2–5847; FRL–4827–3]

Approval and Promulgation of Implementation Plans; Illinois

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: On March 24, 1993, the United States Environmental Protection Agency (USEPA) proposed to approve a January 4, 1989 revision to the Illinois sulfur dioxide (SO_2) State Implementation Plan (SIP), and solicited public comment on the proposed action. This document responds to the public comments received and announces approval of the requested revision, which amends the SIP to provide SO_2 emission limits for the Shell Oil Complex in Roxana, Wood River Township, Illinois. This action also clarifies USEPA's approval of related Illinois SO_2 rules which were included in Illinois' January 4, 1989 submittal but were subsequently revised and resubmitted. The USEPA's approval of these rules satisfies the September 28, 1984 notice of SIP deficiency for Wood River Township.

The USEPA's action is based upon a revision request which was submitted by the State to satisfy the requirements of the Clean Air Act.

EFFECTIVE DATE: This final rulemaking becomes effective on February 28, 1994.

ADDRESSES: A copy of this revision to the Illinois SIP is available here for inspection: Jerry Kurtzweg (ANR–443), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Copies of the SIP revision, public comments on the rulemaking, and other materials relating to this rulemaking are available for inspection at the following address: Regulation Development Branch, Regulation Development Section (AR–18J), U.S. Environmental Protection Agency, Region 5, Chicago, Illinois 60604. (It is recommended that you telephone Mary Onischak at (312) 353–5954, before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Mary Onischak at (312) 353–5954.

SUPPLEMENTARY INFORMATION:

I. Summary of State Submittal

On September 28, 1984, USEPA informed the Governor of Illinois that the Illinois SO_2 SIP was inadequate to protect the National Ambient Air Quality Standards (NAAQS) in Alton and Wood River Townships of Madison County, Illinois, and requested that the State submit revisions to the SIP to address the inadequacy. The determination that the SIP needed to be revised was based on modeling performed by the Illinois Environmental Protection Agency (IEPA) for a regional study which included Madison County. Modeled violations of the NAAQS in Wood River Township were attributed primarily to the Shell Oil refinery complex in Roxana, Illinois. IEPA was able to demonstrate NAAQS attainment in the Wood River area through significant emission reductions at the Shell Oil complex. The Shell Oil emission limits are set forth at 35 Illinois Administrative Code (35 IAC) 214.382, and were submitted to USEPA as a revision to the Illinois SO_2 SIP on January 4, 1989.

On March 24, 1993 (58 FR 15824), USEPA stated that the January 4, 1989 submittal could be approved if Illinois placed a set of recordkeeping and reporting requirements for enforcement purposes into a federally enforceable State operating permit for the Shell Oil Company. Operating permits issued under Illinois' federally enforceable operating permit program, which was approved and incorporated into the Illinois SIP by USEPA on December 17, 1992 (57 FR 59928) at 40 CFR 52.737, are federally enforceable parts of the SIP upon issuance by the State, unless USEPA deems them not federally enforceable. The USEPA transmitted a list of the necessary permit conditions for Shell Oil in a June 12, 1992 letter to the State. On November 10, 1992, the Shell Oil Company applied for an operating permit which would include the recordkeeping and reporting requirements identified by USEPA. On September 1, 1993, a public hearing was held in Wood River, Illinois, to receive comments on the Shell Oil permit. Shell Oil's operating permit (I.D. Number 199090AAA) was issued on November 2, 1993, in accordance with the