employee who has at least 10 years of railroad service but is claiming credit for at least 15 years, the Board will not delay the establishment of an extended benefit period based on 10 years of service but shall extend the ending date of such period if the employee is able to establish credit for 15 years of railroad service.

(c) *Effective date.* An employee acquires 10 years, or 15 years, of railroad service, as the case may be, as of the first day with respect to which creditable compensation is attributable in his 120th, or 180th, month of service.

§ 336.14 Extended benefit period.

(a) *Defined.* An extended benefit period consists of seven consecutive 14-day registration periods in the case of an employee having 10–14 years of railroad service and 13 consecutive 14-day registration periods in the case of an employee having 15 or more years of railroad service.

(b) *Beginning date.* In the case of unemployment benefits, an extended benefit period begins with the first day of unemployment after the day on which the employee exhausts his or her rights to normal unemployment benefits. In the case of sickness benefits, the beginning date is the first day of sickness after the employee exhausts normal sickness benefits. Such first day of unemployment or first day of sickness must be within the same benefit year with respect to which the employee exhausted normal unemployment or normal sickness benefits, as the case may be. However, no extended benefit period may begin on any day of unemployment or sickness prior to the date on which the employee acquired 10 years of railroad service.

(c) *Ending date.* If an employee has 10 but less than 15 years of railroad service, his or her extended benefit period ends on the 97th day after it began. If an employee has 15 or more years of railroad service, his or her extended benefit period ends on the 181st day after it began. If an employee attains age 65 during an extended sickness benefit period, such extended benefit period will terminate on the day next preceding the date on which the employee attains age 65, except that it may continue for the purpose of paying benefits for his or her days of unemployment, if any, during such extended benefit period. If an extended sickness benefit period terminates because the employee has attained age 65 and if at that point the employee has rights to normal sickness benefits, the employee will be paid normal sickness benefits if he or she is otherwise entitled to payment thereof.

(d) *Maximum number of compensable days.* During an extended benefit period consisting of seven consecutive 14-day registration periods, extended benefits may be paid for a maximum of 65 days of unemployment (or 65 days of sickness, as the case may be). During an extended benefit period consisting of 13 consecutive 14-day registration periods, extended benefits may be paid for a maximum of 130 days of unemployment (or 130 days of sickness, as the case may be).

§ 336.15 How to claim extended benefits.

An employee who has 10 or more years of railroad service who exhausts his or her rights to normal unemployment or normal sickness benefits and who wishes to claim extended unemployment or extended sickness benefits may do so by claiming benefits on the forms provided by the Board pursuant to parts 325 or 335 of this chapter. The claim forms provided for this purpose are the same as those provided for claiming normal benefits. No special application for extended benefits is required, and no waiting period applies to the payment of extended benefits.

§ 336.16 Notice to employee.

Upon determining that an employee is eligible for a period of extended unemployment or sickness benefits, the Board will notify the employee of the beginning and ending dates of such extended benefit period.

Dated: January 21, 1994.

By Authority of the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 94–1829 Filed 1–27–94; 8:45 am]

BILLING CODE 7905–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 91C–0432]

Listing of Color Additives for Coloring Sutures; D&C Violet No. 2; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of December 16, 1993, for the final rule that amended the color additive regulations to provide for the safe use of D&C Violet No. 2 to color poliglecaprone 25 (ε-caprolactone/glycolide copolymer) absorbable sutures for general surgery.

DATES: Effective date confirmed: December 16, 1993.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9511.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 15, 1993 (58 FR 60106), FDA amended 21 CFR 74.3602 to provide for the safe use of D&C Violet No. 2 to color poliglecaprone 25 (ε-caprolactone/glycolide copolymer) absorbable sutures for general surgery.

FDA gave interested persons until December 16, 1993, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the final rule published in the **Federal Register** of November 15, 1993, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 721 (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the November 15, 1993, final rule. Accordingly, the amendments promulgated thereby became effective December 16, 1993.

Dated: January 24, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–1885 Filed 1–27–94; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 330

[Docket No. 92N–0454]

RIN 0905–AA06

Labeling of Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its general labeling policy for over-the-

counter (OTC) drug products to allow for the interchangeable use of certain words in labeling required by an OTC drug monograph. Examples of these words include: "doctor" and "physician," "consult" and "ask," and "indications" and "uses." This final rule provides alternate terminology in the labeling of OTC drug products for words that have the same meaning.

EFFECTIVE DATE: February 28, 1994.

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 April 5, 1993 (58 FR 17553), the agency proposed to amend its general labeling policy for over-the-counter (OTC) drug products to allow for the interchangeable use of certain words in the labeling required by an OTC drug monograph. The agency had previously proposed in a number of tentative final monographs and included in a number of final monographs a provision that the words "doctor" and "physician" may be used interchangeably in the labeling of OTC drug products. (See, e.g., §§ 333.150(e), 333.350(e), and 336.50(e) (21 CFR 333.150(e), 333.350(e), and 336.50(e)).) Instead of including this provision in each OTC drug monograph, the agency proposed to include such a provision in § 330.1 (21 CFR 330.1) as part of the general conditions under which an OTC drug is generally recognized as safe, effective, and not misbranded. The agency also proposed that, at manufacturers' discretion, the word "ask" could be substituted for the word "consult," which appears in the directions for many OTC drug monograph ingredients. (See, e.g., §§ 333.150(c)(1), 333.350(c)(2), and 340.50(c)(2) (21 CFR 340.50(c)(2)).) Thus, the agency proposed that the phrases "consult a physician," "consult a doctor," "ask a physician," and "ask a doctor" could be used interchangeably. The agency invited comments and suggestions as to such other terms that could be used interchangeably, i.e., terms general in nature that appear in more than one OTC drug monograph.

One trade association, representing OTC drug manufacturers, and one drug manufacturer submitted comments in response to the agency's proposal. Copies of the comments are on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

I. Summary of the Comments Received

The comment from the trade association agreed with the agency's proposal to allow for the interchangeable use of the words "doctor" and "physician," and the words "consult" and "ask." The comment suggested the following additional sets of alternative terms and gave the following citations, showing inclusion in several OTC drug monographs, as support: (1) "Clean" or "cleanse" (§§ 333.150(d), 333.350(d)(1), and 346.50(d)(1) (21 CFR 346.50(d)(1))); (2) "persist" or "continue" (§§ 341.76(c)(5)(ii), 346.50(c)(7)(iii), 357.150(c)(1), and 357.850(c)(1)(i) (21 CFR 341.76(c)(5)(ii), 346.50(c)(7)(iii), 357.150(c)(1), and 357.850(c)(1)(i))); (3) "chronic" or "persistent" (§§ 336.50(c)(1), 338.50(c)(3), 341.74(c)(2), (c)(3), and (c)(4)(ii) through (c)(4)(iv), and 341.78(c)(1) (21 CFR 338.50(c)(3), 341.74(c)(2), (c)(3), and (c)(4)(ii) through (c)(4)(iv), and 341.78(c)(1))); (4) "assistance" or "help" (§§ 331.30(g), 332.30(c), 341.74(f), and 342.76(c)(5)(i) and (c)(6)(ii) (21 CFR 331.30(g), 332.30(c), 341.74(f), and 342.76(c)(5)(i) and (c)(6)(ii))); and (5) "pulmonary" or "lung" (§§ 336.50(c)(1) and 338.50(c)(3)). The comment stated that, in some instances, the paired terms already appear in the cited regulations and, in other cases, the alternative terms may be better understood by consumers. The comment mentioned the following examples: "Lung" disease may be better understood than the more technical "pulmonary" disease, and "persistent" may be better understood than "chronic." The comment stated its understanding that the rule is intended only to provide a glossary of comparable terms that may be used interchangeably, not to make substantive changes in the underlying required label statements. For example, the comment mentioned that the rule would not permit the term "health professional" as an alternative to the terms "doctor" or "physician," because a "health professional" may include pharmacists, nurses, midwives, and others who are not licensed to practice medicine. The comment requested that the agency clarify that this rule applies only to OTC drug monograph language otherwise required to be declared verbatim in OTC drug product labeling. The comment added that the rule would not apply to or otherwise affect the use of truthful and nonmisleading alternative terms that can be used for monograph indications.

The other comment also proposed that the terms "assistance" and "help" be allowed interchangeably in the general overdose warning, which states: "In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately."

II. The Agency's Final Conclusions

The agency has carefully evaluated the comments' proposals for the interchangeable use of certain terms and concludes that the interchangeable terms suggested by the comments ("clean" or "cleanse," "persist(s)" or "continue(s)," "assistance" or "help," and "pulmonary" or "lung") are acceptable and will help promote better label readability.

In addition, the agency has determined that the terms "indication(s)" or "use(s)" should be allowed to be used interchangeably. The agency considers the term "use(s)" to be simpler and better understood by consumers than the term "indication(s)." The agency is including this option in § 330.1(i).

The agency disagrees with the interchangeable use of the words "chronic" and "persistent." "Chronic," by definition, is of long duration, or may be subject to habit or disease for a lengthy period (Ref. 1). On the other hand, "persistent," by definition, is refusing to let go, insistently repetitive or continuous, or enduring (Ref. 2). While "chronic" is also "persistent," "persistent" is not necessarily "chronic." For instance, a chronic cough denotes one that has gone on for a lengthy period of time, while a persistent cough could be one of recent onset that does not respond to treatment. Thus, a chronic cough and a persistent cough may be the same, or they could be two separate entities. Therefore, interchangeable use of the terms "chronic" and "persistent" is not included in the final rule.

References

(1) "Webster's II New Riverside University Dictionary," Houghton Mifflin Co., Boston, 1984, s.v. "chronic."

(2) "Webster's II New Riverside University Dictionary," Houghton Mifflin Co., Boston, 1984, s.v. "persistent."

This final rule does not make substantive changes in the language required in OTC drug monographs. The rule allows for alternative terminology for certain terms that are sufficiently comparable to be used interchangeably. The rule does not affect the use of truthful and nonmisleading terminology as an alternative to monograph indications in accord with § 330.1(c)(2)(ii) and (c)(2)(iii).

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