Hourly Demand Data By Specified Week, are proposed to be replaced by the following:

Part III Schedule 2: Planning Area Hourly Demand and Forecast Summer and Winter Peak Demand and Annual Net Energy For Load

Respondents, which participate in a national, regional or subregional process for consolidating and ensuring the consistency and accuracy of actual and forecast demand information are required to authorize the national, regional or subregional organization to release that information to the public without conditions and in an easily accessible electronic format.

If the respondent does not participate in the development of national, regional or subregional actual and forecast demand information, it is required to submit its own, equivalent, demand information directly to the Commission along with this report, as follows.

Respondents must submit on a 3.5 inch diskette formatted for the DOS operating system the following data file in ASCII format: the planning area's actual hourly demand, in megawatts, for each hour of the year starting with 12 midnight, January 1, 1993, central standard time. The file should have 8760 records (8784 for leap years).

Also provide on the diskette a file containing the planning area's forecast summer and winter peak demand, in megawatts, and annual net energy for load, in megawatthours, for the next ten years.

[FR Doc. 93-7825 Filed 4-2-93; 8:45 am]

BILLING CODE 6717-01-M

TENNESSEE VALLEY AUTHORITY

18 CFR Part 1301

Freedom of Information Act

AGENCY: Tennessee Valley Authority (TVA).

ACTION: Proposed Rule.

SUMMARY: The Tennessee Valley Authority is proposing to amend its Freedom of Information Act regulations to more accurately reflect its direct reasonable operating costs in searching for and reviewing records requested under the Freedom of Information Act.

DATES: Comments must be received by May 5, 1993.

ADDRESSES: Comments regarding this proposed rule should be sent to Mark R. Winter, TVA, 1101 Market Street (MR 2F), Chattanooga, TN 37402-2801. As a convenience to commenters, TVA will accept public comments transmitted by facsimile ("FAX") machine. The telephone number of the FAX receiver is (615) 751-2902. Receipt of FAX transmittals will not be acknowledged.

FOR FURTHER INFORMATION CONTACT: Mark R. Winter, (615) 751-2523.

SUPPLEMENTARY INFORMATION: TVA is proposing to amend 18 CFR 1301.2(c)(1) to more accurately reflect its direct reasonable operating costs in searching for and reviewing records requested under the Freedom of Information Act. The rates proposed reflect an average rate for the range of TVA pay grades typically involved in responding to Freedom of Information Act requests. For time spent by clerical employees, the charge is currently $8.35 per hour. For time spent by supervisory and professional employees, the charge is currently $19.75 per hour. TVA is proposing to amend the charges to $10.10 per hour and $32.20 per hour, respectively. In conformance with section (a)(4)(A)(iv) of the Freedom of Information Act, as amended, TVA is also proposing to amend 18 CFR 1301.2(d)(2) by reducing the amount of search time that will be provided without charge from 4 hours to 2 hours.

List of Subjects in 18 CFR Part 1301

Administrative practice and procedure, Freedom of Information, Privacy Act, Sunshine Act.

For the reasons set forth in the preamble, title 18, chapter XIII of the Code of Federal Regulations is proposed to be amended as follows:

PART 1301—PROCEDURES

1. The authority citation for part 1301 continues to read as follows:

Authority: 16 U.S.C. 831-831dd, 5 U.S.C. 552.

2. Section 1301.2 is amended by revising paragraph (c)(1) and the first sentence of paragraph (d)(2) to read as follows:

§ 1301.2 Schedule of fees.

* * * * *

(c) * * *

(1) *Search time charges for other than computer searches.* For time spent by clerical employees in searching files, the charge is $10.10 per hour. For time spent by supervisory and professional employees, the charge is $32.20 per hour.

* * * * *

(d) * * *

(2) Except for documents provided in response to a commercial use request, the first 100 pages and the first 2 hours of search time will be provided without charge. * * *

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William S. Moore,

Manager, Information Support Services.

[FR Doc. 93-7610 Filed 4-2-93; 8:45 am]

BILLING CODE 8120-08-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend 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 include "doctor" and "physician," and "consult" and "ask." Thus, the phrase "consult a doctor" could be used interchangeably with the phrases "ask a doctor," "consult a physician," and "ask a physician." This proposal provides alternate terminology in the labeling of OTC drug products.

DATES: Written comments by June 4, 1993. The agency is proposing that the final rule based on this proposal be effective 30 days after the date of its publication in the **Federal Register**

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

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, 301-295-8000.

SUPPLEMENTARY INFORMATION: The agency has proposed in a number of tentative final monographs and has 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, for example, §§ 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 is proposing 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 believes that there are other monograph terms for which substitutes could be used, at

manufacturers' discretion. One example is the word "consult" that appears in the directions for many OTC drug monograph ingredients. (See, for example, §§ 333.150(c)(1), 333.350(c)(2), and 340.50(c)(2); 21 CFR 333.150(c)(1), 333.350(c)(2), and 340.50(c)(2).) The agency believes the simpler term "ask" could be used in its place. "Ask" is shorter and may be better understood by consumers. Thus, the phrases "consult a physician," "consult a doctor," "ask a physician," and "ask a doctor" would be allowed interchangeably.

The agency believes that these terms, and possibly others, could be used interchangeably, and that a provision to this effect should also be included in § 330.1, rather than in each OTC drug monograph. Accordingly, the agency is proposing to amend § 330.1 to provide for the use of certain terms interchangeably in the labeling of OTC drug products. The agency is proposing to add paragraph (i) to § 330.1 as follows:

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) "Doctor" or "physician".

The agency is also aware that other terms included in various OTC drug monographs may be used interchangeably. The agency invites comments and suggestions as to such other terms. The terms selected should be general in nature and appear in more than one OTC drug monograph. After considering the comments and suggestions received, the agency will issue an appropriate proposal in a future issue of the **Federal Register**.

The agency has examined the economic consequences of this proposed rule and determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12291, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354). If this proposed rule becomes a final rule, the labeling options could 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 proposal would have no significant economic impact. The agency concludes that the proposed rule is not a major rule as defined in Executive Order 12291. Further, the agency certifies that the proposed rule, if implemented, 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.

Interested persons may, on or before June 4, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Written comments on the agency's economic impact determination may be submitted on or before June 4, 1993. Three copies of all comments are to be submitted, except that individuals 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.

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, it is proposed that 21 CFR part 330 be 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) "Doctor" or "physician".

* * * * *

Dated: January 15, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–7770 Filed 4–2–93; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 358

[Docket No. 82N–0214]

RIN 0905–AA06

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking to amend 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 proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by June 4, 1993; written comments on the agency's economic impact determination by June 4, 1993. The agency is proposing that the final rule based on this proposal be effective 12 months after the date of its publication in the **Federal Register**.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

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, 301–295–8000.

SUPPLEMENTARY INFORMATION:

I. Background

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 developing this monograph, the agency considered data from five studies conducted to demonstrate the safety and effectiveness of 0.6 percent micronized selenium sulfide in the control of dandruff and seborrheic dermatitis (56 FR 63554 at 63559). Only two of those studies (Protocols CP–CA83 and CP–CA70) can be regarded as well-designed controlled clinical trials.