negotiations its own draft rule? (See generally ACUS Negotiated Rulemaking Sourcebook, 1990, Chapter 6—Negotiating the Rule.)

Before being asked to vote on an Order to Establish A Negotiated Rulemaking, I formally have requested that we have the opportunity to review the Commission staff list of issues, possible options, draft rule, etc. Reviewing the Commission staff documents before considering the draft Notice, and then making sure that the Order specifies precisely what is, and what is not, to be considered by the advisory committee, is the *only* way to ensure that we do not end up with an "unguided institutional missile," or, perhaps even worse, one guided by someone else with differing views.

d. Federal Advisory Committee Act (FACA)

FACA requires that an agency have a general regulation governing advisory committee activities in effect, as a condition precedent to the submission of individual advisory committee charters for review by the General Services Administration (GSA). The GSA final regulations implementing FACA codifies that statutory requirement, as well. The FTC determined that it was required to have the general regulation in place before it initiated action to establish an advisory committee to review its Rule 703. I find nothing in the Negotiated Rulemaking Act that would modify this statutory requirement in FACA, and as it is discussed in the ACUS Sourcebook. Consequently, I would conclude that the Commission should promulgate the general regulation as a first step in any *ex parte* negotiated rulemaking.

I am pleased to note that the Commission staff at the November 27, 1991 Commission Meeting informed the Commission that, concurrent with the public comment period for the instant Notice, Commission staff would take the appropriate steps under the GSA regulations implementing FACA for this reg-neg committee. Those steps are important to ensure that the committee is properly constituted and initiated as a matter of law, before the reg-neg process begins. Any failure to satisfy at the outset all applicable legal requirements, such as the GSA regulations under FACA, would unnecessarily expose the Commission and the reg-neg committee to later criticism and potential challenge.

5. Recommendations

(1) I recommend that FERC consider an alternative approach in the form of a regular NOPR based on internal OGC recommendations for refining the existing regulation, rather than adopt a negotiated rulemaking.

(2) If FERC is going to proceed with a negotiated rulemaking, the Commission should drop any reference to informal rulemakings, and insert in lieu thereof, "The Commission is satisfied that as a matter of law *ex parte* prohibitions do not apply to informal rulemaking and as a matter of policy such prohibitions would be inappropriate. Therefore, the negotiated rulemaking will not consider such prohibitions."

(3) If FERC is going to proceed with a negotiated rulemaking, the Commissioners should be allowed to participate directly in the negotiations.

(4) If FERC is going to proceed with a negotiated rulemaking, there should be no commitment that a consensus recommendation will be promulgated in the NOPR as the proposed rule. Rather, the Commission should only provide assurance that consensus recommendations will be taken into account in our deliberations on the proposed rule and will be reflected in the NOPR. And, a "consensus" must be a true unanimous consensus, including the Commission representatives.

(5) If FERC is going to proceed with a negotiated rulemaking, the Order should specify exactly what's to be negotiated and what's outside the scope; but only after we have the opportunity to review Commission staff draft materials.

(6) If FERC is going to proceed with a negotiated rulemaking, we should satisfy first the FACA requirement for a general advisory committee regulation.

6. Conclusion

I view this Notice as a critical issue for how the Commission will function in the years ahead. I am persuaded that we must retain the ability to discuss general policy (*i.e.*, issues not subject to strict *ex parte* prohibitions in a specific docket) even though the policy issue is involved in particular cases, and to discuss informal rulemakings without any prohibitions based on *ex parte* grounds such as the "significant oral communication" requirement. I hope that FERC can proceed to consider a refinement of the strict *ex parte* rules for adjudications without imposing such prohibitions in informal rulemakings or general policy issues on ourselves or having them *de facto* imposed by the advisory committee.

For these reasons, I concur in part and dissent in part.

Charles A. Trabandt,

Commissioner.

[FR Doc. 91-30244 Filed 12-18-91; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 347

[Docket No. 78N-0021]

RIN 0905-AA06

Skin Protectant Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Reopening of Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking; reopening of administrative record.

SUMMARY: The Food and Drug Administration (FDA) is reopening the administrative record for the rulemaking for over-the-counter (OTC) skin protectant drug products to include data on the ingredient "hard fat." This action is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by February 18, 1992.

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-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 7, 1978 (43 FR 34628) 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 skin protectant drug products together with the recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class.

The agency's proposed regulation, in the form of a tentative final monograph, for OTC skin protectant drug products was published in the **Federal Register** of February 15, 1983 (48 FR 6820). Neither the Panel nor the agency considered "hard fat" as an active ingredient for skin protectant uses in either of these publications.

In the **Federal Register** of August 3, 1990 (55 FR 31776) FDA published a final rule, in the form of a final monograph,

establishing conditions under which OTC anorectal drug products are generally recognized as safe and effective and not misbranded. In that document, FDA included "hard fat" as a "protectant active ingredient" in § 346.14 of the final monograph (21 CFR 346.14). The name "hard fat" has replaced the previously used names: Cocoa butter substitutes, hydrogenated cocoglycerides, and hydrogenated palm kernel glycerides. Hard fat is described in an official monograph in "The United States Pharmacopoeia XXII/The National Formulary XVII" (Ref. 1). The agency found that data submitted in response to the OTC anorectal tentative final monograph demonstrated that 19 grades of ingredients designated commercially as Witepsol ingredients perform in a similar fashion to cocoa butter as a skin protectant. Consequently, the agency classified the Witepsols as monograph protectant ingredients for anorectal use when designated as "hard fat."

On December 1, 1990, the agency received a citizen petition (Ref. 2) requesting that the tentative final monograph for OTC skin protectant drug products be amended to include "hard fat" as a Category I ingredient in such products. The request was based on the agency's action on this ingredient in the final rule for OTC anorectal drug products, as discussed above. The petition requested that the agency reopen the administrative record for the rulemaking for OTC skin protectant drug products to include "hard fat," because the tentative final monograph for those products had been published in 1983. The petition provided suggested labeling for OTC skin protectant drug products containing hard fat as an active ingredient.

FDA has carefully considered the request and believes that it would be appropriate to reopen the administrative record for the rulemaking for OTC skin protectant drug products to include the data and information on hard fat considered in the rulemaking for OTC anorectal drug products. Cocoa butter and hard fat (cocoa butter substitutes) are monograph protectant ingredients in the anorectal final rule. Cocoa butter has been considered in the rulemaking for OTC skin protectant drug products and was proposed as Category I in the tentative final monograph (48 FR 6820 at 6832). Based on agency action in the rulemaking for OTC anorectal drug products, hard fat would be classified as a monograph ingredient in the final monograph for OTC skin protectant drug products. The agency is currently developing this final monograph. Therefore, the agency considers that good cause exists, as stated in 21 CFR 330.10(a)(7)(v), to consider the monograph status of hard fat for skin protectant uses at this time. The labeling for such products, suggested in the petition, will be discussed in the final rule for OTC skin protectant drug products.

Interested persons may on or before February 18, 1992, submit to the Dockets Management Branch (address above) written comments regarding the ingredient hard fat used as a skin protectant active ingredient. Three copies of any 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. Comments received may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

References

(1) "The United States Pharmacopoeia XXII and The National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD p. 1931, 1989.

(2) Comment No. CP1, Docket No. 78N-0021, Dockets Management Branch.

Dated: December 11, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91-30220 Filed 12-18-91; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900-AF41

Schedule for Rating Disabilities—Dental and Oral Conditions

AGENCY: Department of Veterans Affairs.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Department of Veterans Affairs (VA) is issuing an advance notice of proposed rulemaking (ANPRM) concerning that portion of the Schedule for Rating Disabilities which deals with dental and oral conditions. This ANPRM is necessary because of a General Accounting Office (GAO) study and recommendation that the medical criteria in the rating schedule be reviewed and updated as necessary. The intended effect of this ANPRM is to solicit and obtain the comments and suggestions of various interest groups and the general public on necessary additions, deletions and revisions of terminology and how best to proceed with a systematic review of the medical criteria used to evaluate dental and oral conditions.

DATES: Written comments and submissions in response to this ANPRM must be received by VA on or before February 18, 1992.

ADDRESSES: Interested persons and organizations are invited to submit written comments and suggestions regarding this ANPRM to the Secretary of Veterans Affairs (271A), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington DC 20420. All written submissions will be available for public inspection only in the Veterans Service Unit, room 170 at the above address and only between the hours of 8 a.m. and 4:30 p.m. Monday through Friday (except holidays) until February 27, 1992.

FOR FURTHER INFORMATION CONTACT: Bob Seavey, Consultant, Regulations Staff (211B), Compensation and Pension Service, Veterans Benefits Administration, (202) 233-3005.

SUPPLEMENTARY INFORMATION: In December 1988, GAO published a report entitled VETERANS' BENEFITS: Need to Update Medical Criteria Used in VA's Disability Rating Schedule (GAO/HRD-89-28). After consulting numerous medical professionals and VA rating specialists GAO concluded that a comprehensive and systematic plan was needed for reviewing and updating VA's Schedule for Rating Disabilities (38 CFR part 4). The medical professionals noted outdated terminology, ambiguous impairment classifications and the need to add a number of medical conditions not presently in the rating schedule. VA rating specialists noted that for some disorders they would prefer more medical criteria for distinguishing between various levels of severity and that inconsistent ratings may result when unlisted conditions had to be rated by analogy to other listed disorders. GAO recommended that VA prepare a plan for a comprehensive review of the rating schedule and, based on the results, revise the medical criteria accordingly. It also recommended that VA implement a procedure for systematically reviewing the rating schedule to keep it updated. VA agreed to both recommendations, and this ANPRM is one step in a comprehensive rating schedule review plan which will ultimately be converted into a systematic, cyclical review process.

This ANPRM is the first stage in VA's consideration of what regulatory action to take, if any, with respect to revising and updating that portion of the rating schedule dealing with dental and oral