

resolve disputes before the Commission. The Commission will continue to provide training in ADR to Commission staff as appropriate. Also, pursuant to the ADRA and amendments to Federal Acquisition Regulation (41 U.S.C. 405(a)), the Commission will incorporate ADR clauses into its procurement contracts where appropriate. Furthermore, the Commission will develop its ADR policy in consultation with the Administrative Conference of the United States and the Federal Mediation and Conciliation Service.

(c) Even before the enactment of the ADRA, the Commission used ADR in its administrative programs. Past Commission uses of ADR have included attempts at both negotiated rulemaking and a minitrial. Furthermore, under the Magnuson-Moss Warranty Act (15 U.S.C. 2301 *et seq.*), the Commission is responsible for encouraging the use of informal dispute settlement mechanisms as an alternative to litigation on warranty matters, and has established minimum standards to govern the operation of these mechanisms in its Rule on Informal Dispute Settlement Procedures (16 CFR part 703). The Commission has also taken an active role in educating consumers regarding the use and advantages of ADR. Finally, in several administrative cease and desist orders, the Commission has included provisions mandating the use of ADR techniques, such as arbitration, as a means of resolving disputes between consumers and businesses.

(d) The Commission has examined alternative means of resolving disputes in connection with its formal and informal adjudications, rulemakings, enforcement actions, contract administration, litigation brought by or against the Commission, and other actions. Due to the varied nature of Commission disputes, the Commission believes that the question whether to use ADR should be determined on a case-by-case basis by appropriate staff. As the Commission develops experience with ADR, the cost, effectiveness, and quality of outcomes obtained by using ADR processes will be evaluated.

(e) The Commission directs its staff to consider whether a particular dispute might be resolved through the use of ADR, to advise parties to Commission disputes of ADR options where appropriate, and to consider carefully suggestions from parties interested in using ADR. Parties subject to the Commission's enforcement authority are encouraged to suggest the use of ADR processes. In evaluating whether and what type of ADR processes to employ,

all relevant factors should be considered. Factors weighing in favor of the use of ADR in a particular case include the following circumstances:

(1) Communication between the parties has broken down or negotiations are at an impasse;

(2) Adjudication would lead to additional delay or expense;

(3) Neutral evaluation could be of assistance in resolving complicated factual or technical disputes;

(4) Multiple interested parties are involved in the dispute and consensus among them is desirable;

(5) Applicable legal standards are clear; or

(6) Assisted negotiations could help offer solutions that the parties may not generate themselves or could lead to faster resolution of the matter than unassisted negotiations.

(f) As provided in the ADRA, factors weighing against the use of ADR include the following circumstances:

(1) A definitive or authoritative resolution of the matter is required for precedential value and an ADR proceeding is not likely to be accepted generally as an authoritative precedent;

(2) The matter involves or may bear upon significant questions of Government policy that require additional procedures before a final resolution may be made, and an ADR proceeding would not likely serve to develop a recommended policy for the agency;

(3) Maintaining established policies is of special importance so that variations among individual decisions are not increased, and an ADR proceeding would not likely reach consistent results among individual decisions;

(4) The matter significantly affects persons or organizations who are not parties to the proceeding;

(5) A full public record of the proceeding is important, and an ADR proceeding cannot provide such a record; and

(6) The agency must maintain continuing jurisdiction over the matter with authority to alter the disposition of the matter in the light of changed circumstances, and an ADR proceeding would interfere with the agency's fulfillment of that requirement.

(g) To encourage the use of alternative means of dispute resolution, the ADRA protects the confidentiality of settlement communications made by the parties or neutrals in a dispute resolution proceeding. The Commission will interpret the Freedom of Information Act (5 U.S.C. 552) in a manner consistent with the ADRA to avoid public disclosure of settlement

communications made as part of a dispute resolution proceeding.

(h) Agency decisions to use or to refrain from using ADR are not judicially reviewable, except at the instance of a nonparty adversely affected by an arbitral award. 5 U.S.C. 581 (a) and (b)(1).

Authority: 5 U.S.C. 561-581, 15 U.S.C. 41-58.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 94-3086 Filed 2-10-94; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 352, 700, and 740

[Docket No. 78N-0038]

RIN 0905-AA06

Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to March 21, 1994, the comment period on the notice of proposed rulemaking that would establish conditions under which over-the-counter (OTC) sunscreen drug products are generally recognized as safe and effective and not misbranded (May 12, 1993, 58 FR 28194). FDA is taking this action in response to a request to extend the comment period for an additional 40 days to allow more time to comment on this proposal. This reopening of the comment period does not apply to comments on ultraviolet A (UVA) testing, protection, ingredients, and labeling. The comment period for these issues closed on November 8, 1993. Subsequently, the agency extended the comment period until February 7, 1994, in order to have a workshop on these subjects in the spring of 1994. A notice concerning this workshop will appear in a future issue of the *Federal Register*. This proposal is part of the ongoing review of OTC drug products conducted by the FDA.

DATES: Written comments by March 21, 1994.

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, 301-594-5000.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of May 12, 1993 (58 FR 28194), FDA issued a notice of proposed rulemaking (tentative final monograph) to establish the conditions under which OTC sunscreen drug products are generally recognized as safe and effective and not misbranded. Interested persons were given until November 8, 1993, to submit comments on the proposal. In the *Federal Register* of October 15, 1993 (58 FR 53460), the agency extended the comment period until February 7, 1994, for all issues except those related to UVA testing, protection, ingredients, and labeling.

On January 19, 1994, the Cosmetic, Toiletry, and Fragrance Association (CTFA), a trade association, requested that the comment period be further extended by approximately 40 days. CTFA stated that the extension is necessary to provide sufficient time for its board of directors to consider and decide positions that CTFA will take in its comments to the agency. CTFA explained that these issues were to be discussed at a meeting of its executive committee on January 19, 1994. However, the meeting was cancelled as a result of travel difficulties caused by inclement weather in the East and Midwest and the earthquake in Los Angeles. CTFA stated that its board of directors will meet on March 2, 1994, and will address the policy issues at that time. CTFA stated that until the meeting, it is impossible to complete comments to the many significant issues raised in the tentative final monograph. CTFA requested an additional 40 days to provide sufficient time to address the issues still outstanding.

FDA has carefully considered the request and believes that this additional time for comment is in the public interest. Accordingly, the comment period is reopened to March 21, 1994.

This reopening of the comment period does not apply to comments on UVA testing, protection, ingredients, and labeling. The comment period for these issues closed on November 8, 1993, in order to have a workshop on these subjects in the spring of 1994. Comments received on UVA issues will be used to formulate questions and subjects for discussion at the workshop. Prior to and following the workshop, the

administrative record for the rulemaking for OTC sunscreen drug products will be reopened to allow additional submissions of comments and data on UVA issues.

Interested persons may, on or before March 21, 1994, submit to the Dockets Management Branch (address above) written comments regarding all sunscreen drug product proposals with the exception of comments pertaining to UVA testing, protection, ingredients, and labeling. 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.

Dated: February 7, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94-3343 Filed 2-9-94; 10:59 am]

BILLING CODE 4160-01-F

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900-AG71

Claims Based on Exposure to Ionizing Radiation

AGENCY: Department of Veterans Affairs.
ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its adjudication regulations concerning diseases claimed to be the result of exposure to ionizing radiation. This amendment is necessary to implement recommendations by the Veterans Advisory Committee on Environmental Hazards (VACEH) that tumors of the brain and central nervous system be considered "radiogenic." The intended effect of this amendment is to add tumors of the brain and central nervous system to the list of radiogenic diseases for service-connected compensation purposes.

DATES: Comments must be received on or before April 12, 1994. Comments will be available for public inspection until April 22, 1994. This amendment is proposed to be effective on the date of publication of the final rule.

ADDRESSES: Interested persons are invited to submit written comments, suggestions, or objections regarding this amendment to Secretary of Veterans Affairs (271A), Department of Veterans Affairs, 810 Vermont Avenue NW.,

Washington, DC 20420. All written comments received will be available for public inspection only in the Veterans Services Unit, room 170, at the above address between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays), until April 22, 1994.

FOR FURTHER INFORMATION CONTACT: John Bisset, Jr., Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, (202) 233-3005.

SUPPLEMENTARY INFORMATION: Under 38 CFR 1.17(c), when VA determines that a significant statistical association exists between exposure to ionizing radiation and any disease, 38 CFR 3.311 is amended to provide guidelines for the establishment of service connection for that disease. Such a determination is made after receiving the advice of the VACEH based on its evaluation of scientific or medical studies.

In a public meeting on April 22-23, 1993, the VACEH met in Washington, DC. At that meeting, the VACEH reviewed studies by Modan, et al., "Radiation-induced Head and Neck Tumors," *Lancet*, February 23, 1974, pp. 277-279, and Ron, et al., "Tumors of the Brain and Nervous System After Radiotherapy in Childhood," *New England Journal of Medicine* 319: 1033-1039 (1988). Based on this review, the VACEH recommended that tumors of the brain and central nervous system, including, but not limited to, gliomas, astrocytomas, and meningiomas, be added to the list of diseases VA will recognize as being radiogenic. The Secretary has accepted that recommendation and we propose to amend 38 CFR 3.311(b)(2) to implement the Secretary's decision effective the date of publication of the final rule.

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601-612. The reason for this certification is that this amendment would not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance program numbers are 64.109 and 64.110.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Handicapped, Health care, Pensions, Veterans.