testimony, briefs, and other Department of Defense filings.

Dated: June 21, 1982.

Francis A. McDonough,

Deputy Commissioner for Government-wide Management, Automated Data and Telecommunications Service.

[FR Doc. 82-18069 Filed 7-1-82; 8:45 am]

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[F-82-20]

Delegation of Authority to the Secretary of Defense

1. *Purpose.* This delegation authorizes the Secretary of Defense to represent the consumer interests of the executive agencies of the Federal Government in proceedings before the Minnesota Public Utilities Commission involving intrastate telecommunications service rates.

2. *Effective date.* This delegation is effective immediately.

3. *Delegation.*

a. Pursuant to the authority contained in the Federal Property and Administrative Services Act of 1949, 63 Stat. 377, as amended, particularly Sections 201(a)(4) and 205(d) (40 U.S.C. 481(a)(4) and 486(d)), authority is delegated to the Secretary of Defense to represent the consumer interests of the Federal executive agencies before the Minnesota Public Utilities Commission involving the application of the Northwestern Bell Telephone Company in Docket No. P-421/GR-82-203 for an increase in rates for telecommunications services. The authority delegated to the Secretary of Defense shall be exercised concurrently with the Administrator of General Services.

b. The Secretary of Defense may redelegate this authority to any officer, official, or employee of the Department of Defense.

c. This authority shall be exercised in accordance with the policies, procedures, and controls prescribed by the General Services Administration, and shall be exercised in cooperation with the responsible officers, officials, and employees thereof.

d. The Department of Defense shall add the General Services Administration to its service list in this case so that GSA will receive copies of testimony, briefs and other Department of Defense filings.

Dated: June 21, 1982.

Francis A. McDonough,

Deputy Commissioner for Government-wide Management, Automated Data and Telecommunications Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 82N-0154]

FDA Policy Relating to Limitations of Labeling Terminology in Over-the-Counter Drug Monographs; Public Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice of public hearing.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a public hearing will be held on the agency's policy of limiting the terms that may be used in over-the-counter (OTC) drug product's label to the specific terminology included in the applicable final OTC drug monograph. This policy, known as the "exclusivity" policy, has been challenged throughout the OTC drug review process, and the agency has been petitioned for a hearing respecting the policy's implementation in the context of the nighttime sleep-aid and stimulant drug products monographs. Although interested persons are invited to submit comments on any aspect of the exclusivity policy regarding any OTC drug product, the Commissioner of Food and Drugs will structure the hearing to seek answers to the specific questions listed below in this notice.

DATES: Written notices of participation must be filed by August 13, 1982. The public hearing will be held on September 29, 1982, beginning at 9 a.m.

ADDRESSES: The hearing will be held in conference rooms D, E, and F, Parklawn Building, 5600 Fishers Lane, Rockville, MD. Written notices of participation should be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-4960.

SUPPLEMENTARY INFORMATION: The Commissioner will hold a public hearing on the agency's policy relating to limitations on labeling terminology in OTC drug monographs. The hearing will be held on September 29, 1982, beginning at 9 a.m., in conference rooms D, E, and F, Parklawn Building, 5600 Fishers Lane, Rockville, MD.

FDA published the tentative final monographs (proposed regulations) for OTC nighttime sleep-aid and stimulant drug products in the **Federal Register** of June 13, 1978 (43 FR 25544). The tentative final monograph for nighttime sleep-aid drug products stated that the labeled indications for such products "shall be limited to one or more of the following phrases: 'Helps fall asleep', 'For relief of occasional sleeplessness', 'Helps to reduce difficulty in falling asleep.' " The tentative final monograph for stimulant drug products stated that the labeled indication for such products "shall be limited to the following phrase: 'Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness.' " In accordance with FDA policy, all other claims or representations of indications would be excluded from the monograph. Thus, any nighttime sleep-aid or stimulant drug product containing labeling that included claims or representations other than those phrases listed above would be a new drug and/or misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p) and 352). A hearing has been requested to challenge the proposed limitations of labeling terminolgy.

The policy of limiting monograph labeling terminology to specific words and phrases considered and approved by FDA is known as the "exclusivity" policy. It has been the subject of comment throughout the OTC drug review process. With the publication of the tentative final monograph for OTC antacid drug products in the **Federal Register** of November 12, 1973 (38 FR 31260), FDA responded to comments proposing that terms other than those specified in the monograph should be allowed in the product labeling. The agency concluded that the terms recommended by the panel fully met the intent of the regulation. The agency further explained that allowing each manufacturer to select words other than those set forth in the monograph would result in continued consumer confusion and deception (38 FR 31264).

With the publication of the final monograph for OTC antiacid drug products in the **Federal Register** of June 4, 1974 (39 FR 19862), the agency addressed a comment that the language required for a labeling warning should not be mandatory because a manufacturer may wish to use minor variations in words to provide clearer understanding by consumers. The agency responded as follows (39 FR 19868):

> The Commissioner believes that uniformity in labeling language is essential to consumers. For this reason, the combining of warnings is permitted only where it will retain uniform terminology. Allowing minor word variations, or rearrangement of the same words, would result in similar or

confusing warnings which would not be in the best interest of the public.

In the **Federal Register** of March 13, 1975 (40 FR 11718), FDA announced an amendment to the monographs for OTC antacid and antiflatulent drug products. Those monographs previously required that such products have labeling that "represents or suggests" the product as therapy for certain conditions set forth in quotation marks. A comment stated that the phrase "represents or suggests" raised the question whether terms analogous or similar to the quoted conditions could be used. The agency restated the position that allowing each manufacturer to select its own terminology would result in continued consumer confusion and deception. To clarify the effect of the exclusivity policy, FDA amended the monographs by deleting the phrase "represents or suggests" and substituting the requirement that the labeling of the product "identify" the product with only the specified terms. The controversy concerning exclusivity was not, however, abated, even though in subsequent tentative final monographs FDA has consistently expanded the labeling recommended by the panels to include alternative terminology suggested in comments.

Subsequently, comments both supporting and objecting to the exclusivity policy were submitted to a number of OTC drug rulemaking proceedings, including the proposed monograph for OTC nighttime sleep-aid and stimulant drug products. The comments objecting to the limitation on labeling terminology charged that it is unduly restrictive, unconstitutional, and contrary to the purpose of the Federal Food, Drug, and Cosmetic Act in that it prevents manufacturers from using truthful alternative wording. FDA responded to these comments in the tentative final monographs for OTC nighttime sleep-aid and stimulant drug products as follows (43 FR 25554):

> The Commissioner believes that labeling terminology relating to indications for use is inseparable from the scientific and medical determinations made by the panel and by FDA concerning the conditions under which a drug ingredient is safe and effective. If a manufacturer varies the terminology approved in the monograph, it is representing its product as safe and effective for a condition for which the product's ingredients have not been found to be safe and effective, or else it is assuming that the variant terminology means the same thing as the terminology approved in the monograph. To permit this practice would defeat the purpose of the OTC Drug Review. The Commissioner believes that the listed indications provide a concise description of those therapeutic effects that scientists recognize OTC nighttime sleep-aids to have, in language that is clear, accurate, and meaningful to the layman. If alternative wording or synonyms are desired, the agency may be petitioned for their inclusion in the monograph.
>
> The Commissioner rejects the contention that limiting permissible labeling claims to those approved in the monograph is unlawful and unconstitutional because it prohibits use of truthful alternative wording. The purpose of the OTC Drug Review is to determine which claims are truthful and which are not, and ample opportunity is provided to settle the question through the OTC Drug Review and monograph amendment procedures.

The agency further noted, in a response to a comment on the exclusivity policy as it relates to both nighttime sleep-aid and stimulant drug products, that the agency would permit alternative terminology only after approval of an appropriate petition to the agency under § 330.10(a)(12) (21 CFR 330.10(a)(12)) and publication of an amendment to an appropriate monograph (43 FR 25545).

The objections to the exclusivity policy were resubmitted with respect to nighttime sleep-aid and stimulant drug products after publication of the tentative final monographs, and an oral hearing was requested. Because of the frequency with which the issue of exclusivity has been raised and is likely to be raised again with respect to future monographs, FDA is granting the request for a hearing to consider whether the agency's long-stated policy on labeling exclusivity for OTC drugs should be retained, modified, or eliminated. The OTC drug review regulations at § 330.10(a)(8) provide that after reviewing objections filed in response to a tentative final monograph, the Commissioner may, by notice in the **Federal Register**, grant an oral hearing. The procedures for such a hearing are set forth in 21 CFR Part 15; the hearing on exclusivity is granted in accordance with these regulations. The agency has also received a number of requests for hearings on other issues in the nighttime sleep-aid and stimulant drug products rulemaking. Those other hearing requests have not as yet been granted or denied, but are still under consideration.

The scope of the hearing now being granted broadly encompasses all aspects, both practical and legal, of the exclusively policy and its possible alternatives, and participants are invited to comment on any matter related to that policy. The inquiry will be structured, however, to seek answers to the following questions:

(1) Does the government have a substantial interest in restricting the terminology used in the labeling of OTC drug products?

(2) If the government's interest is substantial, does restricting labeling to terminology approved by FDA in a final monograph directly advance this interest?

(3) Is the restriction imposed by the exclusivity policy more extensive than is necessary to serve that interest?

(4) By imposing such a restriction, does the agency exceed its authority under the Federal Food, Drug, and Cosmetic Act?

(5) Is the restriction a prior restraint on free speech that is prohibited by the Constitution?

(6) Should there be limitations on terminology used in the labeling of OTC drug products? If the current policy of exclusivity of labeling should be changed, what changes would be desirable from the standpoints of consumers and marketers? The following alternatives have been identified:

(a) Provide a separate list of approved synonyms maintained on file in the Dockets Management Branch. This alternative would retain the exclusivity policy but provide a simplier and more expeditious means of obtaining additional acceptable language for use in labeling.

(b) Require specific information to be included in a designated area of a product's labeling without deviation from the approved language, but permit manufacturers to use their own synonymous language outside the designated area. This alternative would preserve the exclusivity policy with respect to claims made in the designated area, thus providing consumers with an FDA-approved source of information on the label itself, while at the same time allowing manufacturers the flexibility to employ reasonable interpretive language elsewhere in the product's labeling. The agency believes that this alternative represents a compromise that may incorporate the advantages of the exclusivity policy while avoiding some of its perceived rigidity.

(c) Allow manufacturers to interpret the claims included in a monograph in synonymous language. This alternative would abandon the exclusivity policy. Manufacturers would still be required to employ accurate, nonmisleading terminology, but would not have to obtain FDA's prior approval for the language chosen.

The agency is interested in hearing comments on each of these alternatives.

Interested persons who wish to participate must send a notice of participation on or before August 13, 1982, to the Dockets Management Branch, Food and Drug Administration,

Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. All notices submitted should be identified with the docket number found in brackets in the heading of this notice and should contain the following information: name; address; telephone number; business affiliation, if any, of the person desiring to make a presentation; and the approximate amount of time requested for the presentation.

Groups having similar interests are requested to consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests. After reviewing the notices of participation, FDA will notify each participant of the schedule and time allotted to each person.

The administrative record will remain open for 15 days after the hearing to allow comment on matters raised at the hearing.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701(a), 52 Stat. 1040–42 as amended, 1050–53 as amended, 1055 (21 U.S.C. 321, 352, 355, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.10).

Dated: June 25, 1982.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 82-18016 Filed 7-1-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket Nos. 80P-0501 and 81P-0115]

Coherent, Inc., and Cooper Medical Devices Corp., Microsurgical Argon Laser Intended for Use in Otology; Panel Recommendations on Petitions for Reclassification; Extension of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is extending the time for submitting comments on the notice of panel recommendations on the petitions submitted by Coherent, Inc., and Cooper Medical Devices Corp., to reclassify from class III (premarket approval) into class II (performance standards) the microsurgical argon laser intended for use in otology and for use in otoloaryngology. FDA is taking this action in response to a request for an extension of the comment period.

DATE: Comments by July 10, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Denis L. McCarthy, Bureau of Radiological Health (HFX–460), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3426.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 11, 1982 (47 FR 20188), FDA issued for public comment a notice of panel recommendations on petitions submitted by Coherent, Inc., and Cooper Medical Devices Corp. to reclassify from class III into class II the microsurgical argon laser intended respectively for use in otology and in otolaryngology. The notice provides a 30-day comment period which ends on June 10, 1982. On May 27, 1982, FDA received from Cooper Medical Devices Corp. a request for an extension of the comment period. Cooper states that it is now gathering and evaluating information and clinical data directly relevant to its reclassification petition, but will be unable to complete its evaluation and submit it with the company's comments in the comment period specified in the notice.

FDA agrees that additional time for the preparation and submission of meaningful information and clinical data is in the public interest. Therefore, FDA is granting a 30-day extension of the comment period to July 10, 1982.

Interested persons may, on or before July 10, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding the notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the generic name of the device and the docket numbers found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 28, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-17995 Filed 6-29-82; 10:01 am]

BILLING CODE 4160-01-M

[Docket No. 81N-0200]

Review of Agency Rules

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its current priorities for reviewing the agency's existing rules under the Regulatory Flexibility Act (Pub. L. 96–354) and Executive Order 12291. FDA has undertaken a systematic review of its existing rules for the purpose of identifying and eliminating any unnecessary regulatory burdens on the public.

FOR FURTHER INFORMATION CONTACT: Richard T. Hunt, Regulations Policy Staff (HFC–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3480.

SUPPLEMENTARY INFORMATION:

Background

FDA is committed to eliminating unnecessary regulatory burdens while maintaining appropriate public protection. In the **Federal Register** of July 14, 1981 (46 FR 36333), FDA published a notice announcing its plan for undertaking a systematic review of its existing rules in accordance with requirements of the Regulatory Flexibility Act and Executive Order 12291. The review is designed to identify rules that ought to be revised or revoked because they impose unnecessary burdens on the public generally or on specific segments of the public such as small business. The notice identified FDA's principal criteria to be used in establishing review priorities—the greatest opportunity for cost reduction and the availability of data. Because FDA believes it important that those affected by its regulations have an opportunity to participate in the review, notice also solicited data, information, and views form the public to assist the agency in identifying unduly burdensome regulations and in establishing an appropriate review schedule.

Public Comments

In response to the July 14, 1981 notice, the agency received comments from 125 individuals and organizations concerning over 100 regulations, some of which were the subject of multiple comments. These comments represented a broad spectrum of interests including individual firms, trade associations, health professionals, consumer groups, and academic institutions.

A substantial portion of the comments were concentrated in a few regulatory areas. The targets of greatest public interest were regulations dealing with investigational new drug and new drug applications, food labeling, bioresearch monitoring, and current good manufacturing practice. These regulatory areas accounted for more than 30 percent of the comments received. The majority of comments on these and other regulations recommended revision rather than