new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Interested persons may file with the Hearing Clerk comments on the new data on or before May 27, 1980. In establishing a final monograph, the agency will consider only data submitted prior to the closing of the administrative record. Data submitted after the closing of the administrative record will be considered as a petition to amend the monograph and will be reviewed only after the final monograph is published. The agency emphasizes that interested persons have already had an opportunity to submit comments on the panel report and proposed monograph and objections or requests for an oral hearing to the tentative final monograph. Therefore, comments on data and information already contained in the administrative record or requests for an oral hearing will not be accepted.

Interested persons are invited to submit new data in writing (preferably four copies identified with the Hearing Clerk docket number) on or before March 26, 1980 and written comments (preferably four copies identified with the Hearing Clerk docket number) on or before May 27, 1980. Data and comments should be addressed to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Received data and comments may be seen in the above named office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 19, 1979.

Sherwin Gardner,

Acting Commissioner of Food and Drugs.

[FR Doc. 79-33167 Filed 10-25-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 336

[Docket No. 78N-0036]

Antiemetic Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Reopening of Administrative Record.

SUMMARY: The Food and Drug Administration is reopening the administrative record to permit interested persons to submit further data on those conditions classified in Category II or Category III in the published tentative final monograph establishing conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) antiemetic drug products for human use.

DATES: New data by March 26, 1980. Comments by May 27, 1980.

ADDRESS: Written data and comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) published a tentative final order on OTC anitemetic drug products for human use on July 13, 1979 (44 FR 41064). Interested persons could have filed written objections and requested an oral hearing before the Commissioner of Food and Drugs by August 13, 1979. The tentative final order contained a tentative final monograph and a discussion of those conditions classified in Categories II and III. Under current procedures, a drug product with a Category III condition may remain on the market or may be introduced into the market, after the publication of a final monograph, provided FDA receives notification that studies will be undertaken to obtain the data necessary to resolve the issues that resulted in such classification.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of intent to revise the OTC drug procedural regulations in 21 CFR 330.10 to delete the term "Category III" and the provision that authorizies marketing of an OTC drug product with a Category III condition after a final monograph is established. This action is being taken pursuant to an order of the United States District Court for the District of Columbia in *Cutler* v. *Kennedy*, C.A. No. 77-0734 (D.D.C., July 16, 1979). The court concluded that "* * * the FDA may not lawfully maintain Category III in any form in which drugs with Category III conditions * * * are exempted from enforcement action," (*Cutler, supra*, slip op. at 38). The court issued an order that declared the OTC drug regulations, 21 CFR 330.10, unlawful to the extent that they authorize the marketing of Category III drugs after a final monograph, and enjoined FDA from implementing any portion of the regulations which authorizes such marketing.

Under current procedures, the administrative record closes at the end of the comment period following publication of the panel's report and proposed monograph. Manufacturers wishing to submit data after that time may do so only if they file a petition to reopen the administrative record in accordance with 21 CFR 330.10(a)(10)(ii). Consistent with the court order and in order to simplify the procedures and permit the results of testing to be submitted to FDA as expeditiously as possible, the agency is reopening the administrative record for this category of products for a 5-month period from October 26, 1979 to March 26, 1980, to permit manufacturers to submit, prior to the establishment of a final monograph, new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Interested persons may file with the Hearing Clerk comments on the new data on or before May 27, 1980. In establishing a final monograph, the agency will consider only data submitted prior to the closing of the administrative record. Data submitted after the closing of the administrative record will be considered as a petition to amend the monograph and will be reviewed only after the final monograph is published. The agency emphasizes that interested persons have already had an opportunity to submit comments on the panel report and proposed monograph and objections or requests for an oral hearing to the tentative final monograph. Therefore, comments on data and information already contained in the administrative record or requests for an oral hearing will not be accepted.

Interested persons are invited to submit new data in writing (preferably four copies identified with the Hearing Clerk docket number) on or before March 26, 1980 and comments in writing (preferably four copies identified with the Hearing Clerk docket number) on or before May 27, 1980. Data and comments should be addressed to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Received data and comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 19, 1979.

Sherwin Gardner,

Acting Commissioner of Food and Drugs.

[FR Doc. 79-33169 Filed 10-25-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Parts 338 and 340

[Docket No. 75N-0244]

Nighttime Sleep-Aid and Stimulant Products for Over-the-Counter Human Use; Reopening of the Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Reopening of Administrative Record.

SUMMARY: The Food and Drug Administration is reopening the administrative record to permit interested persons to submit further data on those conditions classified in Category II or Category III in the published tentative final monograph establishing conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) nighttime sleep-aid and stimulant drug products for human use.

DATES: New data by March 26, 1980. Comments by May 27, 1980.

ADDRESS: Written data and comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD–510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) published a tentative final order on OTC nighttime sleepaid and stimulant drug products for human use in June 13, 1978 (43 FR 25544). Interested persons could have filed written objections and requested an oral hearing before the Commissioner of Food and Drugs by August 14, 1978. The tentative final order contained a tentative final monograph and a discussion of those conditions classified in Categories II and III. Under current procedures, a drug product with a Category III condition may remain on the market or may be introduced into the market, after the publication of a final monograph, provided FDA receives notification that studies will be undertaken to obtain the data necessasry to resolve the issues that resulted in such classification.

Elsewhere in this issue of the **Federal Register,** FDA is publishing a notice of intent to revise the OTC drug procedural regulations in 21 CFR 330.10 to delete the term "Category III" and the provision that authorizes the marketing of an OTC drug product with a Category III condition after a final monograph is established. This action is being taken pursuant to an order of the United States District Court for the District of Columbia in *Cutler* v. *Kennedy,* C.A. No. 77–0734 (D.C.C., July 16, 1979). The Court concluded that "* * * the FDA may not lawfully maintain Category III in any form in which drugs with Category III conditions * * * are exempted from enforcement action," (*Cutler, supra,* slip op. at 38). The Court issued an order that declared the OTC drug regulations, 21 CFR 330.10, unlawful to the extent that they authorize the marketing of Category III drugs after a final monograph, and enjoined FDA from implementing any portion of the regulations which authorizes such marketing.

Under current procedures, the administrative record closes at the end of the comment period following publication of the panel's report and proposed monograph. Manufacturers wishing to submit data after that time may do so only if they file a petition to reopen the administrative record in accordance with 21 CFR 330.10(a)(10)(ii). Consistent with the court order and in order to simplify the procedures and permit the results of testing to be submitted to FDA as expeditiously as possible, the agency is reopening the administrative record for this category of products for a 5-month period from October 26, 1979 to March 26, 1980 to permit manufacturers to submit, prior to the establishment of a final monograph, new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Interested persons may file with the Hearing Clerk comments on the new data on or before May 27, 1980. In establishing a final monograph, the agency will consider only data submitted prior to the closing of the administrative record. Data submitted after the closing of the administrative record will be considered as a petition to amend the monograph and will be reviewed only after the final monograph is published. The agency emphasizes that interested persons have already had an opportunity to submit comments on the panel report and proposed monograph and objections or requests for an oral hearing to the tentative final monograph. Therefore, comments on data and information already contained in the administrative record or requests for an oral hearing will not be accepted.

Interested persons are invited to submit new data in writing (preferably four copies identified with the Hearing Clerk docket number) on or before March 26, 1980 and comments in writing (preferably four copies identified with the Hearing Clerk docket number) on or before May 27, 1980. Data and comments should be addressed to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857. Received data and comments may be seen in the above office between 9 a.m. and 4 p.m. Monday through Friday.

Dated: October 19, 1979.

Sherwin Gardner,

Acting Commissioner of Food and Drugs.

[FR Doc. 79–33168 Filed 10–25–79; 8:45 am]

BILLING CODE 4110–03–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 16, 17, and 160

[LR–71–78]

Vinson-Trammell Act; Excess Profits on Contracts for Naval Vessels or Military Aircraft

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the profit limitations of the Vinson-Trammell Act (the "Act") on certain contracts and subcontracts for naval vessels and military aircraft. Generally, the limitations on excess profits on contracts for naval vessels and military aircraft imposed by the Vinson-Trammell Act have been suspended while the Renegotiation Act has been in effect. After the expiration of the Renegotiation Act on September 30, 1976, the provisions of the Act became generally effective. This document proposes to revoke the existing regulations under the Act and to adopt new regulations under the Act. These regulations affect contractors and subcontractors of naval vessels and military aircraft for the Department of Defense.

DATES: Written comments and requests for a public hearing must be delivered or mailed by December 26, 1979. The amendments are proposed to be effective for income taxable years ending after September 30, 1976.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, Attention: CC:LR:T (LR–71–78), Washington D.C. 20224.

FOR FURTHER INFORMATION CONTACT: H. B. Hartley of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224, Attention: CC:LR:T, 202–566–3287, not a toll-free call.

SUPPLEMENTARY INFORMATION:

Background

The Vinson-Trammell Act (10 U.S.C. 2382 and 7300) places limitations on the amount of profit that may be made on contracts or subcontracts for the