Category III condition after publication of a final monograph.

Intent To Propose New Procedures

To carry out the court order, the agency intends to revise 21 CFR 330.10 to delete the provision permitting the marketing of Category III conditions in OTC drug products after a final monograph has been issued. Any data available to resolve the safety or effectiveness issues that resulted in a Category III classification will have to be submitted to FDA during the OTC drug administrative procedure, that is, before the establishment of a final monograph. The OTC drug review process itself provides extensive and adequate time for manufacturers to conduct studies and obtain the data necessary to resolve the issues that resulted in a Category III classification. Manufacturers interested in upgrading Category III conditions may wish to use the findings in a panel's report as a basis on which to plan and initiate the necessary studies. Past experience has shown that FDA has rarely disagreed with a panel's recommendation and upgraded a Category II or III condition without submission of additional data by a manufacturer. In the future, the agency will consider, in publishing a final monograph, only data submitted during the rulemaking period before the closing of the comment period for the tentative final monograph. Data submitted after the closing of the comment period for the tentative final monograph will be considered as a petition to amend the monograph and will be reviewed only after the final monograph is published in the **Federal Register**. The agency will meet with industry representatives at their request to advise them on the adequacy of their proposed protocols. FDA continues to encourages firms to cooperate and work with each other in arranging for the necessary study or studies to avoid unnecessary and repetitive human testing.

Although the court in *Cutler* did not object to use of the term "Cateogory III" during the course of the OTC drug review prior to publication of a final monograph, FDA intends to propose deleting the term wherever it appears in § 330.10. However, the agency believes it imporant that manufacturers know the distinction between the kind of safety or effectiveness issue that resulted in a Category I or II classification and that as to which the panel had insufficient data to make such a classification. In the latter case, the panel and the agency believe that further testing may upgrade the condition in question to Category I. Therefore, the agency intends to propose new language in the OTC regulations that will denote this distinction in the state of the evidence regarding a condition's classification during the rulemaking proceeding. The agency wants to make it clear that it intends to delete the term "Category III" from all future published tentative and final orders.

Under the revised procedure, any drug product that fails to conform to an applicable monograph after its effective date would be liable to regulatory action.

Elsewhere in this **Federal Register**, the agency is publishing notices to reopen the administrative record for three groups of drug products for which tentative final monographs with Category III conditions have been published. This is being done to permit manufacturers to submit new data prior to a final monograph demonstrating the safety and effectiveness of those conditions not classified as Category I.

Dated: October 19, 1979.

Sherwin Gardner,

Acting Commissioner of Food and Drugs.

[FR Doc. 79-33170 Filed 10-25-79; 8:45 am]

BILLING CODE 4110-03-M

---

21 CFR Part 333

[Docket No. 75N-0183]

Topical Antimicrobial 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) topical antimicrobial 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 topical antimicrobial drug products for human use on January 6, 1978 (43 FR 1210). Interested persons could have filed written objections and requested an oral hearing before the Commissioner of Food and Drugs by February 6, 1978. The tentative final order contained a tentative final monograph and a discussion of those conditions classified by the panel 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 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. 770734 (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 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

---

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

---

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.