Lane, Rockville, MD 20857, and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

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 has on numerous occasions received new data and information bearing on OTC drug panel reports and proposed monographs after the closing of the administrative record. Under § 330.10(a)(10)(i) (21 CFR 330.10(a)(10)(i)) the administrative record closes with respect to the submission of new data and information at the end of the comment period following publication of the panel report in the **Federal Register.** The comment period for OTC laxative, antidiarrheal, emetic and antiemetic drug products closed on June 19, 1975. The procedural regulations for OTC drugs, § 330.10(a)(10)(ii) (21 CFR 330.10(a)(10)(ii)), provide that after the closing of the comment period following publication of the panel report, new data and information may be submitted for inclusion into the administrative record only through a petition to reopen the administrative record. In some cases, persons have not submitted such petitions; rather, they have submitted new data and information to the Hearing Clerk as comments on the panel report. In the interest of expediting the OTC drug review and because FDA wishes to consider all pertinent data and information that have been submitted to the Hearing Clerk, Food and Drug Administration, prior to the date of publication of this notice, the agency has concluded that the new data and information, whether or not properly filed, should be available to the agency in developing applicable tentative final and final orders. By this notice, FDA announces that it is treating these submissions, received after the administrative record has closed, as petitions to reopen the administrative record, and is granting the petitions by allowing new data and information contained therein to be included in the administrative record for OTC laxative, antidiarrheal, emetic and antiemetic drug products. This notice serves to inform interested persons of the existence of these data and information and their availability for review at the office of the Hearing Clerk, Food and Drug Administration. Comments on these data and information will not be accepted at this time. However, interested persons will have an opportunity to submit comments and additional new data and information at times to be specified in future **Federal Register** notices.

This action does not preempt or supersede the reopening of the administrative record for antiemetic drug products for an additional period as specified in the **Federal Register** of October 26, 1979 (44 FR 61610). That notice provided an additional period of 5 months, ending on May 27, 1980, during which new data demonstrating the safety and effectiveness of those conditions not classified in Category I may be submitted.

Dated: March 12, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–8491 Filed 3–20–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Parts 338, 340

[Docket No. 75N–0244]

Nighttime Sleep-Aid and Stimulant Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration.

ACTION: Acceptance of data and information into the administrative record.

SUMMARY: This notice advises that the Food and Drug Administration (FDA) reopened the administrative record for over-the-counter (OTC) nighttime sleep-aid and stimulant drug products to allow for consideration of data and information that had been filed with the Hearing Clerk, Food and Drug Administration, after the date that the administrative record officially closed.

ADDRESS: Data and information are on public file in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

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 has on numerous occasions received new data and information bearing on OTC drug panel reports and proposed monographs after the closing of the administrative record. Under § 330.10(a)(10)(i) (21 CFR 330.10(a)(10)(i)) the administrative record closes with respect to the submission of new data and information at the end of the comment period following publication of the panel report in the **Federal Register.** The comment period for OTC nighttime sleep-aid and stimulant drug products closed on March 8, 1976 and the reply comment period closed on April 8, 1976. The procedural regulations for OTC drugs, § 330.10(a)(10)(ii) (21 CFR 330.10(a)(10)(ii)), provide that after the closing of the comment period following publication of the panel report, new data and information may be submitted for inclusion into the administrative record only through a petition to reopen the administrative record. In some cases, persons have not submitted such petitions; rather, they have submitted new data and information to the Hearing Clerk as comments on the panel report. In the interest of expediting the OTC drug review and because FDA wishes to consider all pertinent data and information that have been submitted to the Hearing Clerk, Food and Drug Administration, prior to the date of publication of this notice, the agency has concluded that the new data and information, whether or not properly filed, should be available to the agency in developing a final order. By this notice, FDA announces that it is treating these submissions, received after the administrative record has closed, as petitions to reopen the administrative record, and is granting the petitions by allowing new data and information contained therein to be included in the administrative record for OTC nighttime sleep-aid and stimulant drug products. This notice serves to inform interested persons of the existence of these data and information and their availability for review at the office of the Hearing Clerk, Food and Drug Administration. Comments on these data and information will not be accepted at this time. However, interested persons will have an opportunity to submit comments and additional new data and information at times to be specified in future **Federal Register** notices.

This action does not preempt or supersede the reopening of the administrative record for an additional period as specified in the **Federal Register** of October 26, 1979 (44 FR 61610). That notice provided an additional period of 5 months, ending on May 27, 1980, during which new data demonstrating the safety and effectiveness of those conditions not classified in Category I may be submitted.

Dated: March 12, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-8504 Filed 3-20-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 341

[Docket No. 76N-0052]

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration.

ACTION: Acceptance of data and information into the administrative record.

SUMMARY: This notice advises that the Food and Drug Administration (FDA) reopened the administrative record for over-the-counter (OTC) cold, cough, allergy, bronchodilator, and antiasthmatic drug products to allow for consideration of data and information that had been filed with the Hearing Clerk, Food and Drug Administration, after the date that the administrative record officially closed.

ADDRESS: Data and information are on public file in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

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

SUPPLEMENTARY INFORMATION: The Food and Drug Administration has on numerous occasions received new data and information bearing on OTC drug panel reports and proposed monographs after the closing of the administrative record. Under § 330.10(a)(10)(i) (21 CFR 330.10(a)(10)(i)) the administrative record closes with respect to the submission of new data and information at the end of the comment period following publication of the panel report in the **Federal Register.** The comment period for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products closed on December 8, 1976, and the reply comment period closed January 7, 1977. The procedural regulations for OTC drugs, § 330.10(a)(10)(ii) (21 CFR 330.10(a)(10)(ii)), provide that after the closing of the comment period following publication of the panel report, new data and information may be submitted for inclusion into the administrative record only through a petition to reopen the administrative record. In some cases, persons have not submitted such petitions; rather, they have submitted new data and information to the Hearing Clerk as comments on the panel report. In the interest of expediting the OTC drug review and because FDA wishes to consider all pertinent data and information that have been submitted to the Hearing Clerk, Food and Drug Administration, prior to the date of publication of this notice, the agency has concluded that the new data and information, whether or not properly filed, should be available to the agency in developing a tentative final order. By this notice, FDA announces that it is treating these submissions, received after the administrative record has closed, as petitions to reopen the administrative record, and is granting the petitions by allowing new data and information contained therein to be included in the administrative record for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products. This notice serves to inform interested persons of the existence of these data and information and their availability for review at the office of the Hearing Clerk, Food and Drug Administration. Comments on these data and information will not be accepted at this time. However, interested persons will have an opportunity to submit comments and additional new data and information at times to be specified in future **Federal Register** notices.

Dated: March 12, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-8472 Filed 3-20-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 342

[Docket No. 76N-0482]

Topical Antibiotic Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration.

ACTION: Acceptance of data and information into the administrative record.

SUMMARY: This notice advises that the Food and Drug Administration (FDA) reopened the administrative record for over-the-counter (OTC) topical antibiotic drug products to allow for consideration of data and information that had been filed with the Hearing Clerk, Food and Drug Administration, after the date that the administrative record officially closed.

ADDRESS: Data and information are on public file in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

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 has on numerous occasions received new data and information bearing on OTC drug panel reports and proposed monographs after the closing of the administrative record. Under § 330.10(a)(10)(i) (21 CFR 330.10(a)(10)(i)) the administrative record closes with respect to the submission of new data and information at the end of the comment period following publication of the panel report in the **Federal Register.** The comment period for OTC topical antibiotic drug products closed on June 30, 1977, and the reply comment period closed on August 1, 1977. The procedural regulations for OTC drugs, § 330.10(a)(10)(ii) (21 CFR 330.10(a)(10)(ii)), provide that after the closing of the comment period following publication of the panel report, new data and information may be submitted for inclusion into the administrative record only through a petition to reopen the administrative record. In some cases, persons have not submitted such petitions; rather, they have submitted new data and information to the Hearing Clerk as comments on the panel report. In the interest of expediting the OTC drug review and because FDA wishes to consider all pertinent data and information that have been submitted to the Hearing Clerk, Food and Drug Administration, prior to the date of publication of this notice, the agency has concluded that the new data and information, whether or not properly filed, should be available to the agency in developing a tentative final order. By this notice, FDA announces that it is treating these submissions, received after the administrative record has closed, as petitions to reopen the administrative record, and is granting the petitions by allowing new data and information contained therein to be included in the administrative record for OTC topical antibiotic drug products. This notice serves to inform interested persons of the existence of these data and information and their availability