they pertain to the issuance of a countervailing duty order by the Commissioner of Customs, are hereby waived.

ROBERT H. MUNDHEIM,
General Counsel of the Treasury.

OCTOBER 4, 1977.

[FR Doc.77-24661 Filed 10-7-77;8:45 am]

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

[Docket No. 77C-0126]

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

Annatto; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document confirms the effective date of August 19, 1977, of a regulation concerning the use of annatto in coloring externally applied drugs and in coloring cosmetics generally, including those drugs and cosmetics intended for use in the area of the eye.

DATE: Effective date confirmed: August 19, 1977.

FOR FURTHER INFORMATION CONTACT:

Gerad L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204 (202-472-5740).

SUPPLEMENTARY INFORMATION: A regulation published in the FEDERAL REGISTER of July 19, 1977 (42 FR 36993) amended § 73.1030 (21 CFR 73.1030) and added new § 73.2030 (21 CFR 73.2030) to Subparts B and C, respectively, of Part 73 (21 CFR Part 73) to provide for the safe use of annatto in coloring externally applied drugs and in coloring cosmetics generally, including those drugs and cosmetics intended for use in the area of the eye. The regulation also amended § 81.1 (g) (21 CFR 81.1(g)) by deleting annatto from the provisionally listed colors.

Under the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), notice is given that no objections or requests for hearing were filed in response to the regulation of July 19, 1977. Accordingly, the amendments promulgated thereby became effective on August 19, 1977.

Dated: October 3, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77-29616 Filed 10-7-77;8:45 am]

[4110-03]

SUBCHAPTER D—DRUGS FOR HUMAN USE

[Docket No. 77N-0263]

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

Amendment of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule amends the regulations to extend the time within which interested persons may submit comments on proposed monographs for OTC drug products. Because of the length of most such documents, the present provision for a 60-day comment period is usually not adequate; therefore, the agency is providing for a 90-day comment period.

DATES: Effective November 10, 1977; comments on or before November 10, 1977.

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 OTC drug review regulations in § 330.10(a)(6) (21 CFR 330.10(a)(6)) provide that, after publication of a proposed monograph, interested persons have 60 days within which to file written comments. Because of the voluminous and detailed data appearing in these reports, however, the 60-day comment period has proven to be an unreasonably short time for many persons. Accordingly, the Commissioner of Food and Drugs is extending the comment period on such documents to 90 days.

In consideration of the foregoing, the Commissioner finds for good cause that notice and public procedure is unnecessary because the modification effected by this rule is minor and noncontroversial, and public comment on it is therefore unlikely to be received. Interested persons may, on or before the effective date, file with the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, four copies of written comments, identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the office of the Hearing Clerk between the hours of 9 a.m. and 4 p.m., Monday through Friday. Any changes in this regulation justified by such comments will be the subject of a further amendment.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), § 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs is amended in paragraph (a)(6)(iv) in the third sentence of the undesignated paragraph and in paragraph (a)(10)(i) in the first sentence by changing "60" to "90."

Effective date. This amendment shall be effective November 10, 1977.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: October 3, 1977.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.77-29615 Filed 10-7-77;8:45 am]

[4110-03]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 546—TETRACYCLINE ANTIBIOTIC DRUGS FOR ANIMAL USE

Tetracycline Phosphate Complex and Sodium Novobiocin Capsules

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a supplemental new animal drug application filed by the Upjohn Co., providing revised labeling for a combination new drug used to treat certain upper respiratory tract infections in dogs.

EFFECTIVE DATE: October 11, 1977.

FOR FURTHER INFORMATION CONTACT:

Robert A. Baldwin, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857 (301-443-3420).

SUPPLEMENTARY INFORMATION: In In accordance with section 512(i) of the act (21 U.S.C. 360b(i)), Part 546 is amended to reflect approval of a supplemental new animal drug application (NADA 65-099V) filed by the Upjohn Co., Kalamazoo, Mich. 49001.

The original application, approved prior to the Animal Drug Amendments of 1968, was the subject of a National Academy of Science/National Research Council Drug Efficacy Review (NAS/NRC DESI 107NV), published in the FEDERAL REGISTER of August 12, 1970 (35 FR 12791). The Academy evaluated this