The generic device name index will assist in finding the specific classification regulation for a device classified by more than one classification panel.

ADDRESS: The generic device name index for classification regulations is available from the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Robert S. Kennedy, Bureau of Medical Devices (HFK-401), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7900.

SUPPLEMENTARY INFORMATION: The Medical Device Amendments of 1976 (Pub. L. 94-295, 90 Stat. 539-583), amending the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040 et seq. (21 U.S.C. 301 et seq.)) became law on May 28, 1976. Section 513 of the act (21 U.S.C. 360c) requires the Commissioner of Food and Drugs to classify medical devices into one of three regulatory control classes: class I, general controls; class II, performance standards; and class III, premarket approval. The agency is in the process of publishing in the FEDERAL REGISTER proposed classification regulations along with the recommendations of the various medical device classification panels. The first group of proposed classification regulations to publish concerned neurological devices. These were published in the FEDERAL REGISTER of November 28, 1978 (43 FR 5640).

The agency is reviewing the classification recommendations of the various device classification panels that are organized by medical specialty areas. This review has revealed that a generic name device can be used by several medical specialties under different device brand or descriptive names, causing the device to be reviewed by more than one classification panel. When this is the case, the agency will publish only one proposed classification regulation for the generic name device.

The index that FDA is making available pursuant to this notice is correct as of date of publication. Additional changes in device classification names may still occur before final classification regulations are published. If the need arises, FDA will update the index and publish another notice to announce its availability.

The index shows the Device Registration and Listing Product Code for each device reviewed by a classification panel, along with the corresponding generic device name and classification panel with whose classification regulations the classification of that device will be published in the FEDERAL REGISTER. A copy of the index has been placed on public file in the office of the Hearing Clerk (address below) and may be seen in that office from 9 a.m. to 4 p.m., Monday through Friday. Copies of the index may be obtained upon request from the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Requests should specify the Hearing Clerk docket number found in brackets in the heading of this document.

Dated: February 28, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6587 Filed 3-5-79; 8:45 am]

[4110-03-M]

TRANSFER OF ADMINISTRATIVE RESPONSIBILITY FOR OPHTHALMIC HARD CONTACT LENS SOLUTIONS PREVIOUSLY CONSIDERED OVER-THE-COUNTER DRUGS

Implementation

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces that the Food and Drug Administration (FDA) has transferred administrative responsibility for over-the-counter (OTC) opthalmic hard contact lens solutions from the Bureau of Drugs to the Bureau of Medical Devices. In addition, all related data and information developed by, or submitted to, the Advisory Review Panel on OTC Opthalmic Drug Products have been transferred to the Bureau of Medical Devices. This action was taken to implement the Medical Device Amendments of 1976, under which several products previously regarded as drugs now come within the definition of a medical device intended for human use.

FOR FURTHER INFORMATION CONTACT:

Joseph L. Hackett, Bureau of Medical Devices (HFK-403), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7443.

SUPPLEMENTARY INFORMATION: In a notice published in the FEDERAL REGISTER of April 26, 1973 (38 FR 10306), the Commissioner of Food and Drugs requested the submission of data and information on all OTC ophthalmic drug products. The data and information received in response to the notice have been reviewed by the FDA Advisory Review Panel on OTC Ophthalmic Drug Products under the procedures in § 330.10 (21 CFR 330.10). On May 28, 1976, the Medical Device Amendments of 1976 (Pub. L. 94-295) were enacted. Under these amendments, several products that had been previously regarded as drugs and were under review by the Panel, became medical devices within the expanded definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

In the FEDERAL REGISTER of December 16, 1977 (42 FR 63472), FDA issued a notice of implementation of the transitional provisions of the Medical Device Amendments for articles previously considered new drugs or antibiotic drugs. The notice explained the transitional provisions of the amendments, listed generic types of medical devices previously regarded as drugs, explained which of these types are to be subject to premarket approval requirements, indicated which bureau in FDA regulates the products, and explained how manufacturers and importers can petition for changes in the regulatory classification of medical devices intended for human use. In this notice, FDA stated that ophthalmic lens cleaning (sterilizing) solutions and wetting agents for hard contact lenses were previously considered drugs for which premarket approval was not required, but now fall within the definition of "device."

This document announces that FDA has transferred the administrative responsibility for OTC hard contact lens solutions from the Bureau of Drugs to the Bureau of Medical Devices. In addition, FDA has transferred to the Bureau of Medical Devices the responsibility of reviewing a summary of the findings of the Advisory Review Panel on OTC Ophthalmic Drug Products on the safety, effectiveness, and labeling of these hard contact lens solutions and wetting agents. The Panel has emphasized that the summary is not a definitive review but is only a compilation of its work papers on the subject through September 16, 1978. This summary has been appended to the minutes of the September 15 and 16, 1978 Panel meeting and was made available to the public after Panel approval of the minutes during its December 15 and 16, 1978 meeting. The summary has been prepared independently of FDA and does not necessarily represent the agency's position. The Bureau of Medical Devices will, however, consider this summary in making decisions about the regulation of hard contact lens solutions and wetting agents.

The data and information on hard contact lens solutions and wetting agents that were submitted to FDA in response to the April 26, 1973 notice have been transferred to the Bureau of Medical Devices. Persons who sub-