Generic Drug Monographs (HFD–530), Bureau of Drugs.

Request for Hearing (identify with Docket number appearing in the heading of this notice): Hearing Clerk, Food and Drug Administration (HFC–20), Rm. 4–65.

Requests for the report of the National Academy of Sciences-National Research Council: Data Preparation Branch (HFD–614), Division of Drug Information Resources, Bureau of Drugs.

Other communications regarding this notice: Drug Efficacy Study Implementation Project Manager (HFD–101), Bureau of Drugs.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050–1053, as amended (21 U.S.C. 352, 355)) and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.31) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)).

Dated: August 5, 1976.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc.76–23627 Filed 8–12–76;8:45 am]

[Docket No. 76N–0312; DESI's 7913 and 9130]

CERTAIN STEROID PREPARATIONS FOR OPHTHALMIC AND/OR OTIC USE

Drugs for Human Use; Drug Efficacy Study Implementation; Followup Notice and Opportunity for Hearing

In a notice (DESI 9130; Docket No. FDC–D–221 (now Docket No. 76N–0312)) published in the FEDERAL REGISTER of August 26, 1970 (35 FR 13605), and in a subsequent notice (DESI 7913; Docket No. FDC–D–323 (now also Docket No. 76N–0312)) published in the FEDERAL REGISTER of October 22, 1971 (36 FR 20451), the Food and Drug Administration announced its conclusions that certain steroid preparations described below are effective for the treatment of various inflammatory disorders of the eye and/or ear. The notices also classified the preparations as less than effective (probably effective, possibly effective, and lacking substantial evidence of effectiveness) for certain other indications and provided an opportunity for hearing for the indications concluded at that time to lack substantial evidence of effectiveness. No person submitted data in support of the probably or possibly effective indications, and they are now reclassified as lacking substantial evidence of effectiveness. This notice offers an opportunity for hearing concerning the probably effective and possibly effective indications, which are now reclassified as lacking substantial evidence of effectiveness, and states the conditions for marketing the drugs for the indications for which they continue to be regarded as effective. Persons who wish to request a hearing may do so on or before September 13, 1976.

The notice that follows does not pertain to the indications stated in the August 26, 1970 or the October 22, 1971 notices to lack substantial evidence of effectiveness. No person requested a hearing concerning them, and they are no longer allowable in labeling. Any such product labeled for those indications is subject to regulatory action.

1. NDA 8–765; Cortisone Acetate Ophthalmic Ointment containing 1.5 percent cortisone acetate; The Upjohn Co., 7171 Portage Rd., Kalamazoo, MI 49002.

2. That part of NDA 7–913 pertaining to Cortone Acetate Ophthalmic Suspension containing 0.5 percent cortisone acetate; Merck Sharp & Dohme, Division of Merck & Co., Inc., West Point, PA 19486.

3. NDA 9–018; Hydrocortone Ophthalmic Ointment containing 1.5 percent hydrocortisone acetate and Suspension containing 0.5 percent and 2.5 percent hydrocortisone acetate; Merck Sharp & Dohme.

4. NDA 10–231; Hydrin-2 Ophthalmic Suspension containing 2 percent hydrocortisone acetate; Riker Laboratories, Inc., Subsidiary 3M Co., 19901 Nordhoff St., Northridge, CA 91324.

5. NDA 10–645; Optef Eye Drops containing 0.2 percent hydrocortisone; The Upjohn Co.

6. NDA 9–130; Cortril Ophthalmic Ointment containnig 0.5 percent and 2.5 percent hydrocortisone acetate; Pfizer Laboratories, Division Pfizer Inc., 235 E. 42d St., New York, NY 10017.

7. NDA 9–825; Isopto Hydrocortisone Eye Drops containing 0.5 percent and 2.5 percent hydrocortisone with hydroxypropyl methylcellulose; Alcon Laboratories, Inc., 6201 S. Freeway, Box 1959, Ft. Worth, TX 76101.

8. NDA 10–639; Hydeltrasol Ophthalmic Solution containing 0.5 percent prednisolone sodium phosphate; Merck Sharp & Dohme.

9. NDA 11–028; Hydeltrasol Ophthalmic Ointment containing 0.25 percent prednisolone sodium phosphate; Merck Sharp & Dohme.

10. NDA 13–422; Maxidex Ophthalmic Solution containing 0.1 percent dexamethasone; Alcon Laboratories, Inc.

11. NDA 11–984; Decadron Phosphate Ophthalmic Solution containing 0.1 percent dexamethasone sodium phosphate; Merck Sharp & Dohme.

12. NDA 11–977; Decadron Phosphate Ophthalmic Ointment containing 0.05 percent dexamethasone sodium phosphate; Merck Sharp & Dohme.

The following drug products were not included in the August 26, 1970 or the October 22, 1971 notices, but the conclusions described in this notice are applicable to them.

1. NDA 9–816; Cortef Aectate Ophthalmic and Otic Suspension containing hydrocortisone acetate; The Upjohn Co.

2. NDA 9–817; Cortef Acetate Opthalmic Ointment containing hydrocortisone acetate; The Upjohn Co.

3. That part of NDA 10–439 pertaining to Isopto P.H.N. Opthalmic Solution containing hydrocortisone or hydrocortisone acetate; Alcon Laboratories, Inc.

4. NDA 8–054; Cortogen Ophthalmic Suspension containing cortisone acetate; Schering Corp., Galloping Hill Rd., Kenilworth, NJ 07033.

5. NDA 9–841; Isopto Cortisone Ophthalmic Suspension containing cortisone acetate; Alcon Laboratories, Inc.

6. NDA 10–776; Delta Cortef Eye Solution containing prednisolone acetate; The Upjohn Co.

7. That part of NDA 7–913 pertaining to Cortone Acetate Ophthalmic Ointment containing cortisone acetate; Merck, Sharp & Dohme.

In a notice published in the FEDERAL REGISTER of October 27, 1971 (36 FR 20619), the approval of NDA 7–913 for Cortone Acetate Ophthalmic Ointment and Suspension was withdrawn on the ground of failure to submit required reports under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)). At the time that notice was published, no final conclusions concerning its less than effective (probably effective) indication had been reached. Those conclusions have now been reached, and the purpose of including Cortone (cortisone acetate) Ophthalmic Ointment and Suspension in this notice is to inform all interested persons of such conclusions and offer them the opportunity to request a hearing concerning all issues relating to its legal status.

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. An approved new drug application is a requirement for marketing such drug products.

In addition to the holder(s) of the new drug application(s) specifically named above, this notice applies to all persons who manufacture or distribute a drug product, not the subject of an approved new drug application, that is identical, related, or similar to a drug product named above, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product he manufacturers or distributes. Any person may request an opinion of the applicability of this notice to a specific drug product he manufacturers or distributes that may be identical, related, or similar to a drug product named in this notice by writing to the Food and Drug Administration, Bureau of Drugs, Division of Drug Labeling Compliance (HFD–310), 5600 Fishers Lane, Rockville, MD 20852.

A. *Effectiveness classification.* The Food and Drug Administration has reviewed all available evidence and concludes that the drugs are effective for the indications listed in the labeling conditions below. The drugs now lack substantial evidence of effectiveness for the indications evaluated as probably or possibly effective in the August 26, 1970 and the October 22, 1971 notices. The probably effective indications in the October 22, 1971 notice included the otic in-

dication for dexamethasone sodium phosphate 0.05 percent. This 0.05 percent strength of dexamethasone sodium phosphate now lacks substantial evidence of effectiveness for the otic indication.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and abbreviated supplements to previously approved new drug applications under conditions described herein, except that abbreviated applications are not appropriate for hydrocortisone preparations for otic use containing less than 0.5 percent hydrocortisone since such low strengths have not been shown to be effective for that route of administration. The manufacturer's labeling for the product described in this notice that contains 0.2 percent hydrocortisone does not recommend the product for otic use.

1. *Form of drug.* The drugs are in ointment, aqueous solution, or aqueous suspension forms formulated to be suitable for the intended route of administration. Dosage forms for ophthalmic use shall be sterile.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispensing without prescription." Labels for ophthalmic preparations state that the preparation is sterile.

b. The drug is labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The Indications are as follows:

OPHTHALMIC

Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitis when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation; corneal injury for chemical or thermal burns, or penetration of foreign bodies.

OTIC

(For all except the 0.05 percent dexamethasone sodium phosphate)

Steroid responsive inflammatory conditions of the external auditory meatus, such as allergic otitis externa, selected purulent and nonpurulent infective otitis externa when the hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.

3. *Marketing status.* a. Marketing of drug products that are now the subject of an approved or effective new drug application may be continued provided that, on or before October 12, 1976, the holder of the application submits, if he has not previously done so, (i) a supplement for revised labeling as needed to be in accord with the labeling conditions described in this notice, and (ii) a supplement to provide updating information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD-356H (21 CFR 314.1(c)) to the extent required in abbreviated applications (21 CFR 314.1 (f)).

b. Approval of an abbreviated new drug application (21 CFR 314.1(f)) must be obtained prior to marketing such product. Marketing prior to approval of a new drug application will subject such products, and those persons who caused the products to be marketed, to regulatory action.

C. *Notice of opportunity for hearing.* On the basis of all the data and information available to him, the Director of the Bureau of Drugs is unaware of any adequate and well-controlled clinical investigation, conducted by experts qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and 21 CFR 314.111(a)(5), demonstrating the effectiveness of the drug(s) for the indication(s) lacking substantial evidence of effectiveness referred to in paragraph A. of this notice.

Notice is given to the holder(s) of the new drug application(s), and to all other interested persons, that the Director of the Bureau of Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), withdrawing approval of the new drug application(s) (or, if indicated above, those parts of the application(s) providing for the drug product(s) listed above) and all amendments and supplements thereto providing for the indication(s) lacking substantial evidence of effectiveness referred to in paragraph A. of this notice on the ground that new information before him with respect to the drug product(s), evaluated together with the evidence available to him at the time of approval of the application(s), shows there is a lack of substantial evidence that the drug product(s) will have all the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling. An order withdrawing approval will not issue with respect to any application(s) supplemented, in accord with this notice, to delete the claim(s) lacking substantial evidence of effectiveness.

In addition to the ground for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in 21 CFR 310.6), e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act pursuant to the 201(p) of the act, or pursuant to section 107(c) of the Drug Amendments of 1962; or for any other reason.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Parts 310, 314), the applicant(s) and all other persons who manufacture or distribute a drug product which is identical, related, or similar to a drug product named above (21 CFR 310.6), are hereby given an opportunity for a hearing to show why approval of the new drug application(s) providing for the claim(s) involved should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of a drug product named above and all identical, related, or similar drug products.

If an applicant or any person subject to this notice pursuant to 21 CFR 310.6 elects to avail himself of the opportunity for a hearing, he shall file (1) on or before September 13, 1976, a written notice of appearance and request for hearing, and (2) on or before October 12, 1976, the data, information, and analyses on which he relies to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this proposal to withdraw approval. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing, are contained in 21 CFR 314.200.

The failure of an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by such person not to avail himself of the opportunity for a hearing concerning the action proposed with respect to such drug product and a waiver of any contentions concerning the legal status of such drug product. Any such drug product labeled for the indication(s) lacking substantial evidence of effectiveness referred to in paragraph A. of this notice may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required

who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice of opportunity for hearing shall be filed in quintuplicate. Such submissions, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk (address given below) during working hours, Monday through Friday.

Communications forwarded in response to this notice should be identified with the reference number DESI 7913 or 9130, as appropriate, directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

Supplements (identify with NDA number): Division of Anti-Infective Drug Products (HFD-140), Rm. 12B-45, Bureau of Drugs.

Original abbreviated new drug applications (identify as such): Division of Generic Drug Monographs (HFD-530), Bureau of Drugs.

Request for Hearing (identify with Docket number appearing in the heading of this notice): Hearing Clerk, Food and Drug Administration (HFC-20), Rm. 4-65.

Requests for the report of the National Academy of Sciences-National Research Council: Data Preparation Branch (HFD-614), Division of Drug Information Resources, Bureau of Drugs.

Other communications regarding this notice: Drug Efficacy Study Implementation Project Manager (HFD-101), Bureau of Drugs.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053, as amended (21 U.S.C. 352, 355)) and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.31) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)).

Dated: August 5, 1976.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc.76-23623 Filed 8-12-76;8:45 am]

[FDA-225-76-2003]

FOOD, FOOD CONTAINERS, AND FOOD-RELATED ARTICLES AND EQUIPMENT

Memorandum of Understanding With Consumer Product Safety Commission

The Food and Drug Administration is announcing that a Memorandum of Understanding has been executed with the Consumer Product Safety Commission on July 26, 1976. The purpose of the memorandum is to delineate areas of jurisdiction in the administration of the Consumer Product Safety Act and the Federal Food, Drug, and Cosmetic Act with respect to food, food containers, and food-related articles and equipment.

Pursuant to the announcement published in the FEDERAL REGISTER of October 3, 1974 (39 FR 35697) that future others would be published in the FEDERAL REGISTER, the Commissioner of Food and Drugs is issuing this notice.

MEMORANDUM OF UNDERSTANDING BETWEEN THE CONSUMER PRODUCT SAFETY COMMISSION AND THE FOOD AND DRUG ADMINISTRATION

PURPOSE

The purpose of this Memorandum of Understanding is to delineate the areas of jurisdiction of the respectve signatories for administration of the Consumer Product Safety Act and the Federal Food, Drug, and Cosmetic Act with respect to food, food containers, and food-related articles and equipment.

LEGAL BACKGROUND

A. *CPSC Responsibilities.* The Consumer Product Safety Commission (CPSC) administers the Consumer Product Safety Act (CPSA) (15 U.S.C. 2051 *et seq.*), which was enacted to protect the public from unreasonable risks of injury associated with consumer products. In order to accomplish its mission the Commission is authorized, among other things to issue consumer product safety standards, to establish requirements for warnings and instructions, to declare consumer products banned hazardous products when the public cannot be protected adequately by feasible consumer product safety standards, and to require manufacturers, distributors, and retailers to report potential substantial product hazards associated with consumer products to the Commission, and after opportunity for a hearing, to give notice, and/or repair, replace, or refund the purchase price of the consumer product found to present a substantial product hazard.

The term "consumer product" is defined in section 3(a)(1) of the CPSA (15 U.S.C. 2052(a)(1)) as follows:

The term "consumer product" means any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; but such term does not include—* * *

(I) food. The term "food" as used in this subparagraph means all "food", as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act, * * *.

Thus, articles classified as "food" under the Federal Food, Drug, and Cosmetic Act (FDC Act) (21 U.S.C. 301 et seq.) are not "consumer products" and cannot be regulated under the CPSA.[1] The definition of the term "food" in Section 201 (f) of the FDC Act (21 U.S.C. 321(f)) is, therefore, critical in delineating the scope of CPSC's jurisdiction over "consumer products":

The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

B. *FDA Responsibilities.* The Food and Drug Administration (FDA) of the Department of Health, Education, and Welfare has the responsibility for enforcing the FDC Act which, among other things, prohibits the introduction into interstate commerce of articles of food that are adulterated or misbranded. An "adulterated food", as described in section 402 (21 U.S.C. 342), is one which, because of its contents is, among other things, injurious to health or otherwise unfit for food. A "misbranded food", under section 403 of the Act (21 U.S.C. 343), is one which, among other things, is false or misleading in any particular of its labeling. The purpose of the FDC Act is to ensure that foods are wholesome, safe to eat, produced under sanitary conditions, and labeled and packaged in a truthful, informative, and nondeceptive manner. Under the FDC Act, FDA is also responsible for ensuring that "food additives", as defined in section 201(s) (21 U.S.C. 321(s)), are safe under the conditions of their intended use.

NEED FOR CLARIFICATION

The need for this Memorandum of Understanding arose because of uncertainty concerning the scope of the statutory exclusion under the CPSA for all articles defined as "food" by the FDC Act. The need for clarification is acute because determination of whether a potentially hazardous consumer article is a "food" determines as well whether consumers are to be protected from risk of injury or illness by CPSC pursuant to the CPSA or by FDA pursuant to the FDC Act. Congress recognized the need for cooperation between CPSC and other federal agencies when, in section 29(c) of the CPSA (15 U.S.C. 2078(c)), it provided that the Commission and the heads of other departments and agencies engaged in administering programs related to product safety shall, to the maximum extent practicable, cooperate and consult in order to insure fully coordinated efforts.

While this Memorandum addresses the significant food-related jurisdictional issues encountered since enactment of the CPSA in 1972, it is recognized by the two agencies that additional points needing clarification may arise in the future and that changes in this agreement may become necessary.

AGREEMENT

CPSC and FDA have agreed upon the following principles:

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[1] Substances which are "foods" subject to the FDC Act are also excluded from the definition of "hazardous substance" under section 2(f)2 of the Federal Hazardous Sub- Poison Prevention Packaging Act of 1970 (15