over the Internet. Because some of the answers contained in the document represent FDA's current interpretation of new regulatory requirements, the document constitutes guidance. Therefore, FDA is publishing the document in draft and soliciting public comment. FDA will review received comments and, if appropriate, amend the document in response to comments.

Interested parties may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in the heading of this document. The draft guidance and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This draft guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Alternative methods that comply with the tobacco regulations are acceptable. If a regulated company or person wishes or chooses to use an approach other than that set forth in this guidance document, FDA will, upon request, discuss with that company or person alternative methods of complying with the regulations.

Dated: June 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–17974 Filed 7–9–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0263]

Global Pharmaceutical Corp. et al.; Proposal to Withdraw Approval of Four New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on the agency's proposal to withdraw approval of four new drug applications (NDA's). The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications.

DATES: Written requests for a hearing are due by August 11, 1997; data and information in support of the hearing request are due by September 8, 1997.

ADDRESSES: Requests for a hearing, supporting data, and other comments should be identified with Docket No. 97N–0263 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Olivia A. Vieira, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs or antibiotic drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81). The holders of the NDA's listed in the table below have failed to submit the required annual reports, and have not responded to the agency's request by certified mail for submission of the reports.

Application No.	Drug	Applicant
NDA 9–273	Rauwolfia Serpentina Tablets, 50 milligrams (mg) and 100 mg.	Global Pharmaceutical Corp., Castor and Kensington Aves., Philadelphia, PA 19124–5694.
NDA 11–623	Mucilose Super Powder	European Research Associates, Ltd., Pailinakis Bldg., Elisabeth Ave., P.O. Box N3334, Nassau, N.P., Bahamas.
NDA 12–748	Duotrate (pentaerythritol tetranitrate) Capsules, 45 mg.	Jones Medical Industries, Inc., 1945 Craig Rd., St. Louis, MO 63146.
NDA 16–470	Duotrate (pentaerythritol tetranitrate) Capsules, 30 mg.	Do.

The last two products listed, NDA's 12–748 and 16–470, were named in a notice of opportunity for hearing published in the **Federal Register** of October 14, 1984 (49 FR 40213), under Docket No. 87N–0262, proposing to withdraw the applications, along with other applicants' products, because they lack substantial evidence of effectiveness. In response to that notice, hearings were requested and a hearing was granted (52 FR 32170, August 26, 1987); Jones Medical, the successor in interest to NDA's 12–748 and 16–470, filed a Notice of Participation; on May 10, 1989, the Administrative Law Judge issued his Initial Decision, ordering that NDA's 17–748 and 16–740, and others, be withdrawn; Jones Medical, as well as two other parties, appealed that decision to the Commissioner of Food and Drugs (the Commissioner). If a final order on NDA's 12–748 and 16–470 is issued under the present matter for failing to file required annual reports, the appeal by Jones Medical in Docket No. 87N–0262 will be regarded as withdrawn.

Therefore, notice is given to the holders of the NDA's listed in the table and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) withdrawing approval of the NDA's and all amendments and supplements thereto on the ground that the applicants have failed to submit reports required under § 314.81.

In accordance with section 505 of the act and part 314 (21 CFR part 314), the applicants are hereby provided an opportunity for a hearing to show why the applications listed above should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file: (1) On or before August 11, 1997, a written notice of participation and request for a hearing, and (2) on or before September 8, 1997, the data, information, and analyses

relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for hearing, notice of participation, and request for hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for hearing is not made in the required format or with the required reports, the Commissioner will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: June 19, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–17977 Filed 7–9–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93P–0355]

Gastroenterology-Urology Devices; Denial of Request for Change in Classification of the Ostomy Pouch and Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; denial of petition.

SUMMARY: The Food and Drug Administration (FDA) is denying the petition submitted by Abraham L. Lastnik (hereinafter referred to as the petitioner) to reclassify the ostomy pouch and accessories from class I into class II. The agency is denying the petition because there is no new information, in the form of valid scientific evidence, that general controls currently used in the production of these devices are not sufficient to assure the safety and effectiveness of the devices. This notice also summarizes the basis for the agency's decision.

EFFECTIVE DATE: July 10, 1997.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–5072.

SUPPLEMENTARY INFORMATION:

I. Classification and Reclassification of Devices Under the Medical Device Amendments of 1976

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), as amended by the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA's classification of a device is determined by the amount of regulation necessary to provide reasonable assurance of the safety and effectiveness of a device. Except as provided in section 520(c) of the act (21 U.S.C. 360j(c)), FDA may not use confidential information concerning a device's safety and effectiveness as a basis for reclassification of the device from class III into class II or class I.

Under the amendments, devices were classified into class I (general controls) if there was information showing that the general controls of the act were sufficient to provide reasonable assurance of safety and effectiveness; into class II (performance standards) if general controls were insufficient to provide reasonable assurance of safety and effectiveness, but there was sufficient information to establish a performance standard that would provide such assurance; and into class III (premarket approval) if there was insufficient information to support placing a device into class I or class II, and the device was a life-sustaining or life-supporting device or was for a use that is of substantial importance in preventing impairment of human health, or if the device presented a potential unreasonable risk of illness or injury.

FDA has classified most generic types of devices that were on the market before the date of the amendments (May 28, 1976) (generally referred to as preamendments devices) under the procedures set forth in section 513(c) and (d) of the act through the issue of classification regulations into one of these three regulatory classes. Under section 513(c) and (d) of the act, FDA secures expert Panel recommendations on initial device classifications for generic types of devices. FDA then considers the Panel's recommendations and, through notice and comment rulemaking, issues classification regulations.

Devices introduced into interstate commerce for the first time after May 28, 1976, are by statute automatically classified into class III under section 513(f) of the act. These devices may be reclassified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Those devices that FDA finds to be substantially equivalent to a class I or II generic type of device are thereby classified in the same class as the predicate device.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. Section 513(e) of the act provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based on ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person.

The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when a device was originally classified, as well as information not