not be accepted as proof of timely mailing.)

2. Late Applications

Applications that do not meet the criteria in 1.A. or 1.B. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

A complete program description, information on application procedures, an application package, and business management technical assistance may be obtained from Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mail Stop E–15, Atlanta, Georgia 30305, telephone (404) 842–6575, Email address vxm7@cdc.gov. The announcement will be available on one of two Internet sites on the publication date: CDC's home page at http://www.cdc.gov, or at the Government Printing Office home page (including free access to the **Federal Register**) at http://www.access.gpo.gov.

Programmatic technical assistance may be obtained from Dr. Richard Steketee or Dr. Marta Gwinn, Division of HIV/AIDS Prevention, National Center for HIV, STD, TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mail Stop E–46, Atlanta, Georgia 30333, telephone (404) 639–2090. Eligible applicants are encouraged to call before developing and submitting their application. Please refer to Announcement Number 797 when requesting information.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report: Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report: Stock No. 017–001–00473–1) referenced in the Introduction from the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: July 3, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–18062 Filed 7–9–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreement for a National Center for the Prevention of Childhood Agricultural Injury, Program Announcement 737: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Disease, Disability, and Injury Prevention and Control SEP: Cooperative Agreement for a National Center for the Prevention of Childhood Agricultural Injury, Program Announcement 737.

Time and Date: 8:30 a.m.-4:30 p.m., August 4, 1997.

Place: Corporate Square Building 11, Conference Room A, Corporate Square Boulevard, Atlanta, Georgia 30326.

Status: Closed.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 737.

The meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463.

Contact Person for More Information: Ann Cronin, Office of Extramural Coordination and Special Projects, National Institute for Occupational Safety and Health, CDC, M/S D36, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–2277.

Dated: July 03, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–18061 Filed 7–9–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0261]

Frequently Asked Questions About the New FDA Tobacco Regulations: Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration is announcing the availability of a draft guidance entitled ''Frequently Asked Questions About the New FDA Tobacco Regulations.'' The draft guidance is intended to address the questions most frequently asked by retailers, consumers, and others about the age and identification requirements of the final rule restricting the sale of cigarettes and smokeless tobacco to protect children and adolescents.

DATES: Submit written comments on the draft guidance by September 8, 1997.

ADDRESSES: The draft guidance entitled ''Frequently Asked Questions About the New FDA Tobacco Regulations,'' is available on the Internet at http://www.fda.gov/, or a paper copy may be ordered free of charge by calling 1–888–FDA–4KIDS.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Anne M. Kirchner, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, rm. 14–72, Rockville, MD 20857, 301–827–0867.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 28, 1996 (61 FR 44396), FDA issued a final rule to restrict the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents (21 CFR part 897). The final rule covers three general classes of nicotine-containing tobacco products: Cigarettes, loose cigarette tobacco, and smokeless tobacco. The final rule applies to manufacturers, distributors, retailers, and importers who make, distribute, sell, and import such products.

Since February 28, 1997, the final rule has prohibited retailers from selling cigarettes, loose cigarette tobacco, or smokeless tobacco to persons under the age of 18, and has required retailers to verify the age of customers under the age of 27 by checking an identification (ID) card which contains the bearer's photograph and birth date.

Before the age and ID requirements took effect, FDA officials held a series of public meetings in 10 metropolitan areas and produced a national videoconference to explain the new requirements and to answer questions from retailers, consumers, public health officials, and others. FDA agreed to make available written answers to the questions most frequently asked at these meetings.

The draft guidance that FDA is making available answers these questions, as well as questions that FDA has received on its toll-free hotline and

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