Respondents	Number of respondents	Number of responses	Average hour burden per response
Directly Funded CBOs	184	1	30/60
Indirectly Funded CBOs	1816	1	30/60

Dated: January 2, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–475 Filed 1–8–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1669]

Electronic Filing of Drug Registration and Listing Information: Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is seeking volunteers to participate in a pilot project involving the electronic filing of drug registration and listing information, as described in FDA's regulations. Manufacturers, repackers, and relabelers who engage in the manufacture, preparation, propagation, or processing of human or veterinary drugs and human biological products are required under current regulations to submit a listing of every product in commercial distribution. This information is currently submitted in paper format. FDA is developing an electronic system for submitting the required information, and is seeking volunteers to test the pilot system.

DATES: Submit written requests to participate in the pilot project by February 8, 2001. Comments on this pilot project can be submitted at any time.

ADDRESSES: Submit written requests to participate and comments regarding this pilot project to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: James R. Hunter, Food and Drug Administration, Center for Drug Evaluation and Research (HFD–9), 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779, e-mail: hunterj@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under current FDA's regulations (part 207 (21 CFR part 207)), manufacturers, repackers, and relabelers who engage in the manufacture, preparation, propagation, compounding, or processing of human or veterinary drugs and human biological products must register annually with FDA by submitting Form FDA 2656 (Registration of Drug Establishment). In addition, registrants must update their product listing information by using Form FDA 2657 and/or Form FDA 2658 every June and December, or at the discretion of the establishment, when any change occurs. This entire process is currently done manually (i.e., with a paper process). This process is very labor intensive and time consuming. FDA is trying to streamline the process by developing an electronic system in which registrants could automatically register and list, as well as provide updates.

The purpose of the pilot project is twofold. First, the pilot project will test FDA's systems for receiving electronic filings under part 207. Second, the pilot project will provide volunteers with experience in using the prototype system that will enable them to provide technical feedback to FDA about the system.

II. Pilot Project Description

The pilot project is part of FDA's efforts to implement electronic filing. Eventually, FDA staff expects to recommend that FDA require electronic filings under part 207. Participants in this pilot project will have the opportunity not only to assist FDA in making its determination on electronic filing, but also to familiarize themselves with the process at an early stage of development.

A. Initial Approach

Initially, a limited group of voluntary participants will take part in testing the electronic filing prototype. This group will be incrementally expanded during the pilot project to ensure that as many volunteers as possible get the opportunity to participate and that all functional components of the system are adequately tested. The initial group of participants will include manufacturers, repackers, relabelers, and private label distributors of human prescription and over the counter drug and biological products and manufacturers of veterinary drug products that currently have more than 25 products listed with the agency. During the pilot project, information submitted will be made available to the public by the agency via the Internet at http://www.fda.gov/cder. Participants in the pilot project will be asked to test specific aspects of the electronic filing system and to provide technical feedback.

B. Scope

Existing registration and listing requirements will not be waived, suspended, or modified for purposes of this pilot project. Thus, participants must continue to submit paper documents in accordance with FDA's existing filing requirements (part 207). The paper copy will serve as the official copy under existing regulations during the pilot project.

The pilot project will test a prototype for electronic filing over the Internet of information to fulfill the requirements of section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360).

Written requests to participate in the pilot project should be submitted to the Dockets Management Branch (address above) and identified with the docket number found in brackets in the heading of this document. Include the participants name, company name, company address, and telephone number. In addition, include in your written request to participate the number of products you currently have listed with the agency, the number of establishments you currently have registered with the agency, the type of products you process (i.e., human, biologic, or veterinary), the process(es) you perform (i.e., manufacture, repackage, relabel, distribute), and the kind of products you process (i.e., prescription, over the counter, active pharmaceutical ingredients (bulk), or, homeopathic).

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this pilot project. Two copies of any comment are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will

consider comments in making its determination on electronic filing and in drafting a guidance document for submitting drug registration and listing information electronically. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 5 p.m., Monday through Friday.

Dated: December 29, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–534 Filed 1–8–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Adenoviral Vector Safety; Public Meeting and Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Adenoviral Vector Safety'' and a workshop of the ''Adenoviral Standards Working Group.'' The purpose of the public meeting and workshop is to discuss the scientific and technological issues related to developing voluntary industry reference standards for adenoviral vectors used to deliver human gene therapies. The voluntary industry reference standards will be used to help ensure the safety of adenoviral vectors intendedfor use in humans.

Date and Time: The public meeting and workshop will be held on February 1, 2001. The Adenoviral Vector Safety meeting will be held from 9:30 a.m. to 12 noon.

The Adenoviral Standards Working Group workshop will be held from 1 p.m. to 5 p.m.

Location: The Adenoviral Vector Safety meeting will be held at the Wilson Auditorium, National Institutes of Health, Bldg. 1, 8600 Rockville Pike, Bethesda, MD 20894.

The Adenoviral Standards Working Group workshop will be held at the National Institutes of Health, Bldg. 29B, Conference Rooms A, B, and C, 8600 Rockville Pike, Bethesda, MD 20894.

Contact: Steven R. Bauer, Center for Biologics Evaluation and Research (HFM–521), Food and Drug Administration, Bldg. 29B, rm. 2NN11, Bethesda, MD 20894, 301–827–0684, FAX 301–827–0449, or e-mail: bauer@cber.fda.gov.

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, fax number, and e-mail address) to Steven R. Bauer (address above) by Friday, January 19, 2001. There is no registration fee for the meeting or workshop. Seating is limited, therefore, interested parties are encouraged to register early. Registration at the site will be done on a space available basis on the day of the meeting and workshop, beginning at 8:30 a.m. If you need special accommodations due to a disability, please contact Steven R. Bauer at least 7 days in advance.

Agenda: The Adenoviral Vector Safety meeting will provide a forum for all members of the public to express their concerns about adenoviral vector safety and explore alternatives for enhancing the safety of adenoviral vectors.

The Adenoviral Standards Working Group workshop is cosponsored by FDA's Center for Biologics and Research (CBER) and the Williamsburg BioProcessing Foundation. The workshop will be of primary interest to public health professionals developing new human gene therapy products and manufacturers contemplating the production of such products. The objectives of the workshop are to: (1) Select adenoviruses to use as voluntary reference standards for adenoviral vectors used for human gene therapy products; (2) describe the conditions and facilities to be used when producing bulk quantities of a voluntary reference standard; (3) establish characterization protocols for voluntary reference standards; and (4) address other issues related to voluntary reference standards for adenoviral vectors.

Transcripts: Transcripts of the Adenoviral Vector Safety meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript will also be available on the Internet at http://www.fda.gov/cber/minutes/workshop-min.htm.

Dated: December 29, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–531 Filed 1–8–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Psychopharmacologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 14 and 15, 2001, 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Sandra I. Titus or Lauren W. Parcover, Center for Drug Evaluation and Research (HFD 21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area) code 12544. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 14, 2001, the committee will consider the safety and efficacy of new drug application (NDA) 21–253, Zyprexa® (olanzapine intramuscular, Eli Lilly, Inc.), proposed for the rapid control of agitation. On February 15, 2001, the committee will consider the safety and efficacy of NDA 20–919, Zeldox™ (ziprasidone mesylate intramuscular, Pfizer, Inc.), proposed for the acute control and short-term management of the agitated psychotic patient.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 7, 2001. Oral presentations from the public will be scheduled each day between approximately 1 p.m. to 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 2, 2001,