

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1669]

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Display Date	<u>1 8 01</u>
Publication Date	<u>1 9 01</u>
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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 [*insert date 30 days after date of publication in the Federal Register*]. 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.

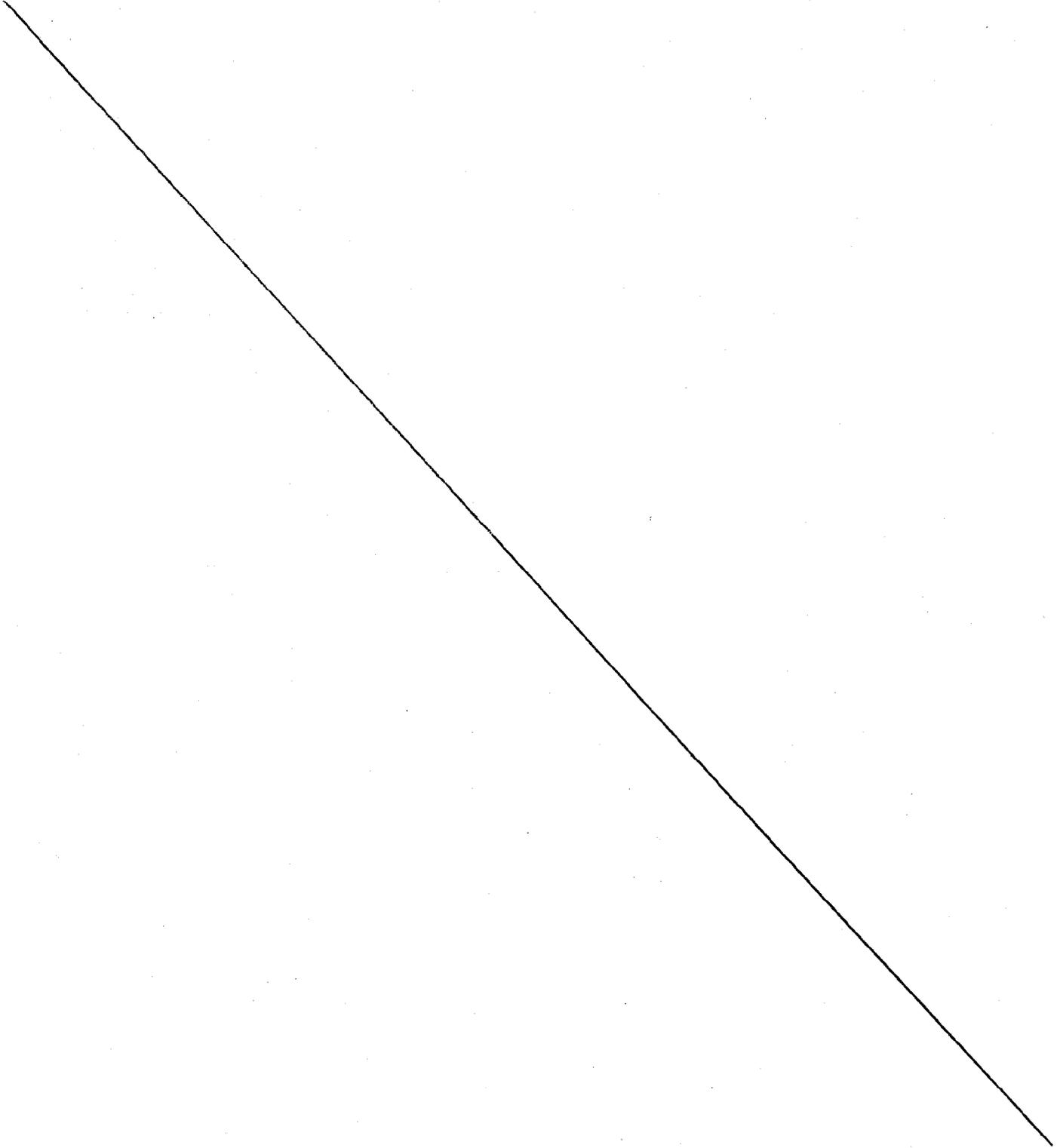
B. Scope

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).

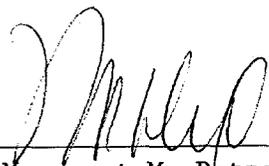
Written requests to participate in the pilot project should be submitted to the Dockets Management Branch (address above) and identified with the docket number found in brackets in the heading of this document. Include the participants name, company name, company address, and telephone number. In addition, 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: 12/29/00
December 29, 2000.



Margaret M. Dotzel,
Associate Commissioner for Policy.

**CERTIFIED TO BE A TRUE
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[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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