

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0192]

DMB

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Draft Guidance for Industry on Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution." The draft guidance is intended to assist establishments that are required to register ("registrants") and submit listing information for drugs and biological products in obtaining and submitting the necessary forms to meet registration and listing requirements; this draft guidance will also assist those private label distributors that are not required to register, but elect to submit designated information directly to FDA. FDA proposes to make available through the Internet, rather than through conventional mail, the following registration and listing forms: Form FDA 2656 (Registration of Drug Establishment), Form FDA 2656e (Annual Update of Drug Establishment), Form FDA 2657 (Drug Product Listing), and Form FDA 2658 (Registered Establishments' Report of Private Label Distributors).

DATES: Submit written comments on this draft guidance document by [*insert date 60 days after date of publication in the Federal Register*]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label

to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

For human drugs: Kathy Smith, Center for Drug Evaluation and Research (HFD-90), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-1086.

For biological drugs: Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373, yetter@cber.fda.gov.

For veterinary drugs: Lowell Fried, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0165, lfried@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under part 207 (21 CFR part 207), as authorized and required by section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) and sections 351 and 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 262 and 264), establishments (e.g. manufacturers, repackers, and relabelers) engaged in the manufacture, preparation, propagation, compounding, or processing of human drugs, veterinary drugs, and biological products, with certain exceptions, are required to register and submit listing information.

Under part 207, these “registrants” use Form FDA 2656 to submit establishment registration information and to submit annual re-registration information (FDA had also used Form FDA 2656e for annual re-registration, but this form will no longer be necessary); private label distributors use Form FDA 2656 to obtain a labeler code; registrants and, in some cases, private label distributors use Form FDA 2657 to submit listing information for drugs and biological products

and to update listing information; and registrants use Form FDA 2658 to submit listing information for private label distributors (FDA has also used the compliance verification report for updating listing information). Registrants will use new Form FDA 3356 to submit establishment and listing information for those human cells, tissues, and cellular and tissue-based products regulated as drugs and/or biological products under the act and section 351 of the PHS Act beginning January 21, 2003.

If a registrant or private label distributor prefers to receive any of these forms through conventional mail, they may direct such requests to the designated agency contacts. Under the draft guidance, information previously submitted on Form FDA 2656e would be submitted on Form FDA 2656. Distribution of these forms through the Internet will reduce administrative costs to the agency. The draft guidance also contains registration information applicable to human cells, tissue, and cellular and tissue-based product establishments.

The draft guidance explains that, unless specifically requested otherwise, FDA is discontinuing the conventional mailing of these forms to registrants and private label distributors. These forms are available on the Internet. Registrants, and if appropriate, private label distributors must continue to submit completed forms to FDA in accordance with the registration and listing requirements in part 207. The draft guidance explains where to obtain the forms on the Internet, how to make changes to information, and where to submit completed forms.

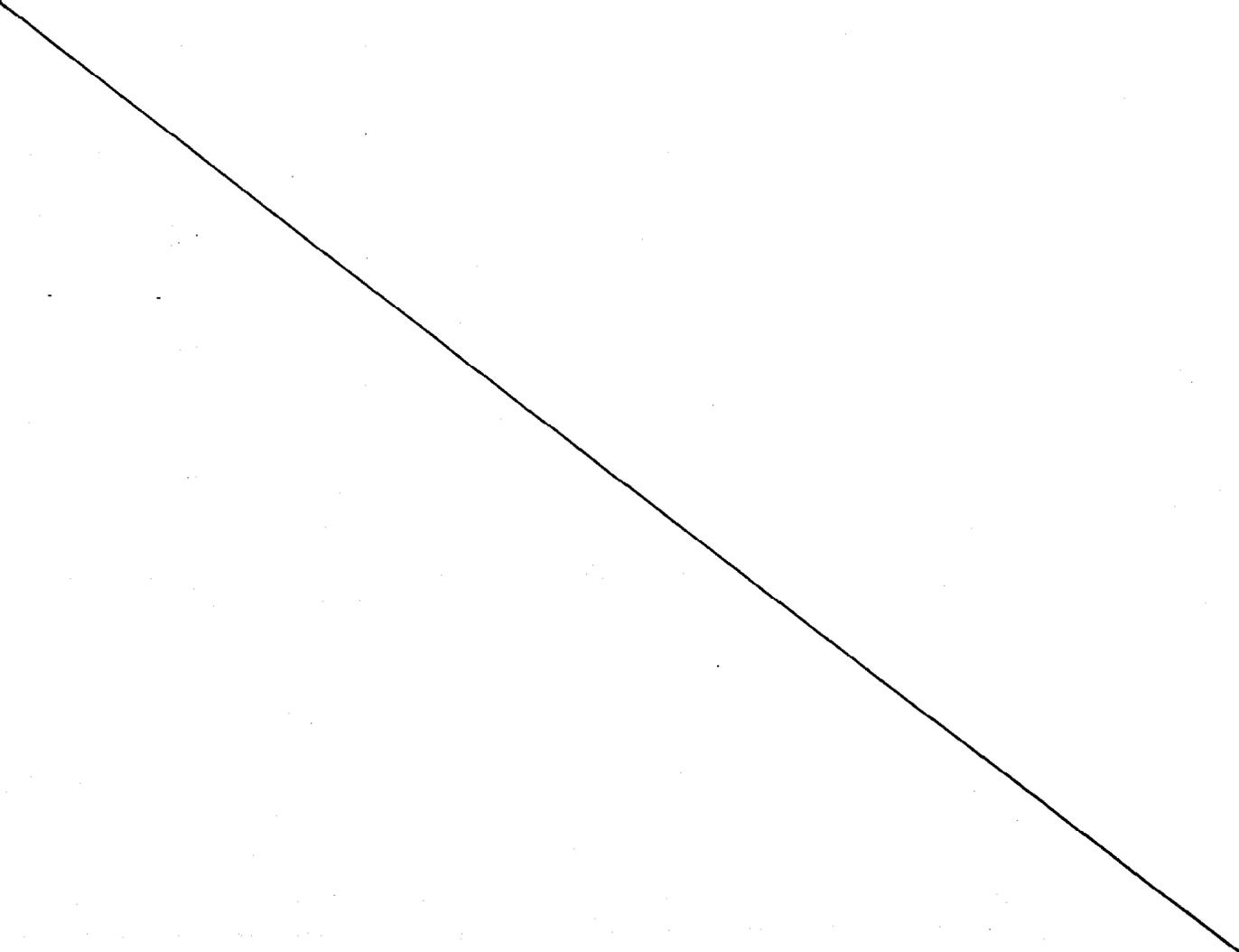
Internet availability of these forms (instead of availability by conventional mail) is part of an agency initiative to use modern technology to facilitate the submission of establishment registration and listing information. FDA is developing software to make possible the electronic submission of the requisite registration and listing information for drugs and biological products. The agency plans to propose rulemaking that would revise the requirements for registration and listing and would require registrants to submit this information electronically.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance represents

the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments regarding the draft guidance. Written comments should be submitted to the Dockets Management Branch (address above). Two copies of any comments 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Comments may also be submitted electronically on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select the relevant "docket number" and follow the directions. Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>.

Dated: _____

5/7/01
May 7, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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