



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2000-D-0103]

Botanical Drug Development; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Botanical Drug Development.” This guidance describes FDA’s current thinking on appropriate development plans for botanical drugs to be submitted in new drug applications (NDAs) and specific recommendations on submitting investigational new drug applications (INDs) in support of future NDA submissions for botanical drugs. In addition, this guidance provides general information on the over-the-counter (OTC) drug monograph system for botanical drugs. Although this guidance does not intend to provide recommendations specific to botanical drugs to be marketed under biologics license applications (BLAs), many scientific principles described in this guidance may also apply to these products. This draft guidance revises the guidance for industry entitled “Botanical Drug Products” issued in June 2004.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft

guidance by [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002.

Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sau L. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4144, Silver Spring, MD 20993-0002, 301-796-2905, Sau.Lee@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Botanical Drug Development.” This guidance describes the Center for Drug Evaluation and Research’s current thinking on appropriate development plans for botanical drugs to be submitted in NDAs and specific recommendations on submitting INDs in support of future NDA submissions for botanical drugs. In addition, this guidance provides general information on the OTC drug monograph system for botanical drugs. Although this guidance does not intend to provide

recommendations specific to botanical drugs to be marketed under BLAs, many scientific principles described in this guidance may also apply to these products.

This guidance specifically discusses several areas in which, due to the unique nature of botanical drugs, the Agency finds it appropriate to apply regulatory policies that differ from those applied to nonbotanical drugs, such as synthetic, semi-synthetic, or otherwise highly purified or chemically modified drugs, including antibiotics derived from microorganisms. Because this guidance focuses on considerations unique to botanical drugs, policies and recommendations applicable to both botanical and nonbotanical drugs are generally not covered in this document.

This guidance revises the final guidance for industry entitled “Botanical Drug Products” issued in June 2004. The general approach to botanical drug development has remained unchanged since that time; however, based on improved understanding of botanical drugs and experience acquired in the reviews of NDAs and INDs for these drugs, specific recommendations have been modified and new sections have been added to better address late-phase development and NDA submission for botanical drugs.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on botanical drug development. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The guidance explains the circumstances under which FDA regulations require approval of an NDA for marketing a botanical drug product and when such a product may be marketed under an OTC drug monograph. The regulations governing the preparation and submission of an NDA are in part 314 (21 CFR part 314), and the guidance does not contain any recommendations that exceed the requirements of these regulations. FDA has estimated the information collection requirements resulting from the preparation and submission of an NDA, and OMB has approved the burden under OMB control number 0910-0001. FDA anticipates that any NDAs submitted for botanical drug products would be included under the burden estimates approved by OMB for part 314.

The regulations on the procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing OTC drug monographs, are set forth in § 330.10 (21 CFR 330.10). FDA believes that any botanical drug products that may be eligible for inclusion in an OTC drug monograph under current § 330.10 have already been or presently are being considered for such inclusion.

The guidance also provides scientific and regulatory guidance to sponsors on conducting clinical investigations of botanical drugs. The regulations governing the preparation and

submission of INDs are in part 312 (21 CFR part 312). The guidance does not contain any recommendations that exceed the requirements in those regulations. FDA has estimated the information collection requirements resulting from the preparation and submission of an IND under part 312, and OMB has approved the reporting and recordkeeping burden under OMB control number 0910-0014.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.