4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0007]

Product Development under the Animal Rule, Revised Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled "Product Development Under the Animal Rule." When human efficacy studies are neither ethical nor feasible, FDA may rely on adequate and well-controlled animal efficacy studies to support approval of a drug or licensure of a biological product under the Animal Rule. This revised draft guidance replaces the 2009 draft guidance for industry entitled "Animal Models--Essential Elements to Address Efficacy Under the Animal Rule" and addresses a broader scope of issues for products developed under the Animal Rule. Once finalized, this guidance is intended to help potential sponsors (industry, academia, and government) understand FDA's expectations for product development under the Animal Rule.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this revised draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the revised draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug

Administration, 10001 New Hampshire Ave., Hillandale Building, rm. 4147, Silver Spring, MD 20993-0002; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0022. Send one self-addressed adhesive label to assist that office in processing your requests. The revised draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the revised draft guidance to http://www.regulations.gov.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: Rosemary Roberts, Office of Counter-Terrorism and Emergency Coordination, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, Mailstop 2163, Silver Spring, MD 20993-0002, 301-796-2210; or Cynthia Kelley, Office of the Director, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7204, Silver Spring, MD 20993-0002, 240-402-8089.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 21, 2009 (74 FR 3610), FDA announced the availability of a draft guidance for industry entitled "Animal Models--Essential Elements to Address Efficacy Under the Animal Rule," which identified the critical characteristics (essential data elements) of an animal model to be addressed when developing drug or biological products for approval or licensure under the Animal Rule. The 2009 draft guidance is available to the

public on FDA's Web site at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

This notice announces the availability of a revision to that draft guidance. The revised draft addresses a broader scope of issues for products developed under the Animal Rule. Based on written comments to the 2009 draft guidance and comments expressed at the related FDA public meeting held on November 5, 2010, FDA broadened the scope of the guidance to discuss product development under the Animal Rule. The revised draft guidance is intended to help potential sponsors understand FDA's expectations for product development under the Animal Rule.

The revised draft guidance has been placed in a new category/subject area, Animal Rule, and can be found under Guidances (Drugs) at the following Web link: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

New information addressing FDA's current thinking for studies related to the development of products under the Animal Rule is included in the revised draft guidance. Section III discusses regulatory considerations, including product development plans, access to investigational drugs during a public health emergency, communications with FDA, and animal model qualification program. General expectations for Animal Rule-specific studies are discussed in section IV, including a discussion of ensuring data quality and integrity. Additional information regarding the selection of an effective dose of the investigational drug for humans is discussed in section V. Design considerations for adequate and well-controlled efficacy studies in animals are described in section VI, which includes a discussion on general principles and dose selection in animals. Special considerations for vaccines and for cellular and gene therapies are outlined in sections VII.A and B, respectively. An additional checklist for the elements of an

adequate and well-controlled animal efficacy study protocol is provided in section X. General principles for the care and use of animals in biomedical research and types of animal care interventions are explained in Appendices A and B, respectively. Finally, general expectations for natural history studies are described in Appendix C.

This revised 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 product development under the Animal Rule. 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. Paperwork Reduction Act

This revised draft guidance refers to previously approved collections of information that 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 collection of information in 21 CFR part 312 (investigational new drug applications) has been approved under OMB control number 0910-0014. The collection of information in 21 CFR part 314 (new drug applications) has been approved under OMB control number 0910-0001. The collection of information resulting from special protocol assessments has been approved under OMB control number 0910-0470. The collection of information resulting from formal meetings between applicants and FDA has been approved under OMB control number 0910-0429. The collection of information resulting from Good Laboratory Practices has been approved under OMB control number 0910-0119. The collection of information resulting from current good manufacturing practices has been approved under OMB control number 0910-0139.

III. 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.

IV. Electronic Access

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

Dated: May 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-12807 Filed 06/02/2014 at 8:45 am; Publication Date: 06/03/2014]