4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Product Development Under the Animal Rule; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "Product Development Under the Animal Rule." When human efficacy studies are not ethical and field trials are not 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 This guidance finalizes the 2014 revised draft guidance for industry "Product Development Under the Animal Rule." It is intended to help potential stakeholders (industry, academia, and government) understand FDA's expectations for product development under the Animal Rule.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2009-D-0007 for "Product Development Under the Animal Rule; Guidance for Industry; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this 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; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. This guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Rosemary Roberts, Counter-Terrorism and Emergency Coordination Staff, Office of the Center Director, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, rm. 2155, 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

FDA is announcing the availability of a guidance for industry entitled "Product Development Under the Animal Rule." In the Federal Register of June 3, 2014 (79 FR 31950), FDA announced the availability of a revised draft guidance for industry entitled "Product Development Under the Animal Rule," intended to help potential stakeholders understand FDA's

expectations for product development under the Animal Rule (see 21 CFR 314.600 through 314.650 for drugs and 21 CFR 601.90 through 601.95 for biological products). The 2014 revised draft guidance replaced the 2009 draft guidance for industry entitled "Animal Models--Essential Elements to Address Efficacy Under the Animal Rule" (74 FR 3610) and addressed a broader scope of issues for products developed under the Animal Rule. The comment period for the revised draft guidance closed on August 4, 2014. We reviewed all comments received and considered them in finalizing the revised draft guidance. This guidance finalizes the revised draft guidance issued on June 3, 2014.[1]

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on product development under the Animal Rule. 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. Paperwork Reduction Act

This 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

[1] Adequate and well-controlled animal efficacy studies are required under the Animal Rule. As a policy, FDA is committed to the exploration of non-animal testing methods.

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. Electronic Access

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

Dated: October 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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