investigators and sponsors. FDA requires this information for tracking and oversight purposes. Investigators are required to maintain records, including correspondence and reports concerning the study, records of receipt, use or disposition of devices, records of each subject's case history and exposure to the device, informed consent documentation, study protocol, and documentation of any deviation from the protocol. Sponsors are required to maintain records including correspondence and reports concerning the study, records of shipment and disposition, signed investigator agreements, adverse device effects information, and, for a nonsignificant risk device study, an explanation of the nonsignificant risk determination, records of device name and intended use, study objectives, investigator information, investigational review board information, and statement on the extent that good manufacturing practices will be followed.

For a nonsignificant risk device investigation, the investigators' and sponsors' recordkeeping and reporting burden is reduced. Pertinent records on the study must be maintained by both parties, and reports are made to sponsors and institutional review boards (IRBs). Reports are made to FDA only in certain circumstances, *e.g.,* recall of the device, the occurrence of unanticipated adverse effects, and as a consequence of certain IRB actions. The estimate of the burden is based on the number of IDEs received in recent years.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Waivers—812.10	1	1	1	1	1
IDE Application—812.20, 812.25, and 812.27	356	1	356	80	28,480
Supplements—812.35 and 812.150	356	12	4,272	6	25,632
Treatment IDE Applications—812.36(c)	1	1	1	120	120
Treatment IDE Reporting—812.36(f)	1	1	1	20	20
Total					54,253

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total Hours
Original—812.140	356	1	356	10	3,560
Supplemental—812.140	356	12	4,272	1	4,272
Nonsignificant—812.140	356	1	356	6	2,136
Total					9,968

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Reports for Nonsignificant Risk Studies—812.150	1	1	1	6	6

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27420 Filed 10–27–15; 8:45 am]

BILLING CODE 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

[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.

(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. 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.

[FR Doc. 2015–27361 Filed 10–27–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0142]

Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route; Guidance for Industry and Review Staff; 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 and review staff entitled ''Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route.'' The guidance provides recommendations concerning the evaluation of the nonclinical safety of reformulated drug products or products being used by an alternate route. It is intended for use by interested individuals in industry and reviewers within the Center for Drug Evaluation and Research (CDER). The goals of this guidance are to foster and expedite the development of reformulated drug products or the use of previously approved drugs by alternate routes, communicate to industry current CDER thoughts pertaining to safety data needed to support these drug products, and increase uniformity within CDER on expectations for the nonclinical development of reformulated drug products or products being used by an alternate route. This guidance finalizes the draft guidance of the same name published on March 7, 2008.

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–2008–D–0142 for ''Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route; Guidance for Industry and Review Staff.'' 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.