

licensure pathway for biological products demonstrated to be biosimilar to or interchangeable with a reference product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, sets forth the requirements for an application for a proposed biosimilar product and an application or supplement for a proposed interchangeable product. Under section 351(k) of the PHS Act, a proposed biological product that is demonstrated to be biosimilar to a reference product can rely on certain existing scientific knowledge about the safety, purity, and potency of the reference product to support licensure, and this is reflected in the approach to biosimilar product labeling.

In this draft guidance, FDA outlines its recommendations for biosimilar product labeling. A demonstration of biosimilarity means, among other things, that FDA has determined that there are no clinically meaningful differences between the proposed product and the reference product in terms of safety, purity and potency. Accordingly, biosimilar applicants should incorporate relevant data and information from the reference product labeling, with appropriate product-specific modifications as described in the draft guidance.

We invite comment on the draft guidance, including whether patient labeling (e.g., Patient Information, Medication Guide, and Instructions for Use) should include a biosimilarity statement similar to the statement described in section IV.C.1 of the draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on labeling for biosimilar products. 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. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations.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 (PRA) of 1995 (44 U.S.C. 3501–3520). The collections of information under 21 CFR part 601 for the submission of a biologics license application under section 351(k) of the PHS Act have been

approved under OMB control number 0910–0719; the collections of information under 21 CFR 201.57 for the submission of labeling have been approved under OMB control number 0910–0572; the collections of information under 21 CFR part 600 for the submission of adverse experience reporting for licensed biological products and general records have been approved under OMB control number 0910–0308; and the collections of information under 21 CFR part 600 for the submission of MedWatch reporting forms (FDA Form 3500 and FDA Form 3500A) have been approved under OMB control number 0910–0291.

III. Electronic Access

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

Dated: March 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0938 (formerly FDA–2003–D–0034 and 2003D–0061)]

Comparability Protocols—Chemistry, Manufacturing, and Controls Information for New Animal Drugs; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#156) entitled “Comparability Protocols—Chemistry, Manufacturing, and Controls Information for New Animal Drugs.” This document provides recommendations to applicants on preparing and using comparability protocols for postapproval changes in chemistry, manufacturing, and controls (CMC) information. It is intended to provide recommendations to industry regarding comparability protocols that would be submitted in new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), or

supplements to these applications. This guidance also applies to comparability protocols submitted in investigational new animal drug (INAD), generic investigational new animal drug (JINAD), and veterinary master file (VMF) submissions that are referenced in applications. FDA is providing this guidance in response to requests from those interested in using comparability protocols.

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–2016–D–0938 for “Comparability

Protocols—Chemistry, Manufacturing, and Controls Information for New Animal Drugs.” 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 the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0696, dennis.bensley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 25, 2003 (68 FR 8772), FDA published the notice of availability for a draft guidance for industry entitled “Comparability Protocols—Chemistry, Manufacturing, and Controls Information,” giving interested persons until June 25, 2003, to comment on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes include describing comparability protocols submitted in CMC (J)INAD technical data submissions or (J)INAD protocols without substantial data. In accordance with the performance goals and procedures for the ADUFA and AGDUFA reauthorizations for fiscal years 2014 through 2018, comparability protocols may be submitted as comparability protocols without substantial data in a (J)INAD file. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated February 2003 only as it applies to the preparation and submission to the Center for Veterinary Medicine of comparability protocols for postapproval changes in CMC information for new animal drugs.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on Comparability Protocols—Chemistry, Manufacturing, and Controls Information for New Animal Drugs. 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.

III. 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 collections of information in 21 CFR part 514 have been approved under OMB control number 0910-0032; the collections of information in section 512(n)(1) of the FD&C Act (21 U.S.C.

360b) have been approved under OMB control number 0910-0669.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: March 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 041

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled “Modifications to the List of Recognized Standards, Recognition List Number: 041” (Recognition List Number: 041), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit electronic or written comments concerning this document at any time. These modifications to the list of recognized standards are effective April 4, 2016.

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