4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-0868]

Development and Submission of Near Infrared Analytical Procedures; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Development and Submission of Near Infrared Analytical Procedures." This draft guidance provides recommendations to applicants of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) regarding the development and submission of near infrared (NIR) analytical procedures used during the manufacture and analysis of pharmaceuticals. This draft guidance only pertains to the development and validation of NIR analytical procedures and does not provide recommendations concerning the set up and qualification of NIR instruments or their maintenance and calibration.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: John L. Smith, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1757.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Development and Submission of Near Infrared Analytical Procedures." This draft guidance provides recommendations to applicants of NDAs and ANDAs regarding the development and submission of NIR analytical procedures used during the manufacture and analysis of pharmaceuticals (including raw materials, in-process materials and intermediates, and finished products). It also provides recommendations regarding how the concepts described in the International Conference on Harmonisation (ICH) guidance for industry, "Q2(R1) Validation of Analytical Procedures: Text and Methodology" (http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm265700.

htm) and "PAT--A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance" (http://www.fda.gov/downloads/Drugs/Guidances/ucm070305.pdf) can be applied to the development, validation, and submission of NIR analytical procedures.

This draft guidance only pertains to the development and validation of NIR analytical procedures and does not provide recommendations concerning the set up and qualification of NIR instruments or their maintenance and calibration.

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 the submission and development of NIR analytical procedures. 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 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 collections of information in 21 CFR part 314 for NDAs, ANDAs, supplements to applications, and annual reports have been approved under OMB control number 0910-0001.

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 or http://www.regulations.gov.

Dated: March 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-07266 Filed: 3/30/2015 08:45 am; Publication Date: 3/31/2015]