

The third comment asserted that we underestimated the reporting burden of the NDIN procedures under § 190.6 by failing to take into account the recommendations in the draft guidance entitled “Dietary Supplements: New Dietary Ingredient Notifications and Related Issues” (the 2011 draft guidance) (available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm257563.htm>). FDA announced the availability of the 2011 draft guidance for comment in a notice published in the **Federal Register** of July 5, 2011 (76 FR 39111).

Although we agree with the commenter that information collection recommendations in guidance are subject to the PRA, we intend to meet our PRA obligations in that regard separately at a later time. The 2011 draft guidance was published solely for the purpose of seeking comment, and it has not been made final. Moreover, FDA intends to publish a revised draft guidance for comment later this year, and the revised draft guidance will supersede the 2011 draft guidance. Although we expect the revised draft guidance to be followed by a final guidance, there will be an interim period where no guidance on NDINs is in effect. The purpose of the current

PRA proceeding is to seek comment on and obtain OMB approval for the NDIN collections of information in effect during this interim period, which are those found in the FDA’s NDIN regulations at § 190.6 and in the electronic NDIN submission forms that we have made available for comment. After publishing a revised draft guidance on NDINs and related issues, we intend to publish a 60-day notice inviting comment on the proposed collections of information associated with that document. At that time, we will carefully evaluate all comments we receive.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
190.6	55	1	55	20	1,100

¹ There are no operating and maintenance costs associated with this collection of information.

We believe that the burden of the premarket notification requirement on industry is limited and reasonable because we are requesting only safety and identity information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in compliance with the FD&C Act. In the past, commenters have argued that our burden estimate is too low. We carefully considered the issue and believe that burden estimates of greater than 20 hours per notification likely include the burden associated with researching and generating safety data for a new dietary ingredient. Under section 413(a)(2) of the FD&C Act, a dietary supplement that contains a new dietary ingredient is deemed to be adulterated unless there is a history of use or other evidence of safety establishing that the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement. This requirement is separate from and additional to the requirement to submit a premarket notification for the new dietary ingredient. FDA’s regulation on NDINs, § 190.6(a), requires the manufacturer or distributor of the dietary supplement, or of the new dietary ingredient, to submit to FDA the information that forms the basis for its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. Thus, § 190.6 only requires the

manufacturer or distributor to extract and summarize information that should have already been developed to meet the safety requirement in section 413(a)(2) of the FD&C Act. We estimate that extracting and summarizing the relevant information from what exists in the company’s files and presenting it in a format that meets the requirements of § 190.6 will take approximately 20 hours of work per notification. However, we seek comments on this estimate. We encourage comments offering alternative burden estimates to include documentation to support the alternative estimate.

We further estimate that 55 respondents will submit 1 premarket notification each. We base our estimate of the number of respondents on notifications received over the past 3 years, which averaged about 55 notifications per year.

Dated: February 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-0230]

Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices.” This draft guidance provides industry and Agency staff with recommendations regarding the technical performance assessment data that should be provided for regulatory evaluation of a digital whole slide imaging (WSI) system. This draft guidance is not final nor is it in effect at this time.

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 of 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 May 26, 2015.

ADDRESSES: An electronic copy of the guidance document is available for

download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nicholas Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5570, Silver Spring, MD 20993-0002, 301-796-4310; or Aldo Badano, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 3116, Silver Spring, MD 20993-0002, 301-796-2534.

SUPPLEMENTARY INFORMATION:

I. Background

Recent technological advances in digital microscopy, in particular the development of whole slide scanning systems, have accelerated the adoption of digital imaging in pathology, similar to the digital transformation that radiology departments have experienced over the last decade. FDA regulates WSI systems manufacturers to ensure that the images produced for clinical intended uses are safe and effective for such purposes. Essential to the regulation of these systems is the understanding of the technical performance of the components in the imaging chain, from image acquisition to image display and their effect on pathologist’s diagnostic performance and workflow.

This draft guidance provides industry and Agency staff with recommendations regarding the technical performance assessment data that should be included for regulatory evaluation of a WSI. This document does not cover the clinical submission data that may be necessary to support approval or clearance. The

guidance provides our suggestions on how to best characterize the technical aspects that are relevant to WSI performance for their intended use and determine any possible limitations that might affect their safety and effectiveness.

II. Significance of 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 Agency’s current thinking on technical performance assessment of digital pathology WSI devices. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of “Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400053 to identify the guidance you are requesting.

IV. 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 of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120, the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231, and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910-0485.

V. 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>.

Dated: February 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Pediatric Ethics Subcommittee of the Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Ethics Subcommittee of the Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency regarding ethical protections for children in FDA-regulated clinical trials.

Date and Time: The meeting will be held on Monday, March 23, 2015 from 8:30 a.m. to 4:30 p.m.

Location: Doubletree by Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910. Answers to commonly asked questions, including information regarding special accommodations due to a disability, visitor parking, and transportation, may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993, 301-796-0885, email walter.ellenberg@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-