announced the availability of a draft guidance entitled “Draft Guidance on Qualification of Biomarker—Galactomannan in studies of Treatments of Invasive Aspergillosis.” The Agency received one comment during the public comment period which was supportive of the qualification of this biomarker. This guidance finalizes the draft guidance issued in October 2014.

This guidance provides qualification recommendations for the use of Galactomannan detection in serum and/or BAL fluid as the sole microbiological criterion to classify patients with hematologic malignancies and recipients of allogeneic hematopoietic stem cell transplants and who also have radiologic evidence suggestive of invasive fungal infection (Ref. 1) as having probable IA for enrollment in clinical trials.

Specifically, this guidance provides the COU for which this biomarker is qualified through the CDER Biomarker Qualification Program. Qualification of this biomarker for this specific COU represents the conclusion that analytically valid measurements of the biomarker can be relied on to have a specific use and interpretable meaning. This biomarker can be used by drug developers for the qualified COU in submission of INDs, NDAs, and BLAs without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker.

“Qualification” means that the use of this biomarker in the specific COU is not limited to a single, specific drug development program. Making the qualification recommendations widely known and available for use by drug developers will contribute to drug innovation, thus supporting public health.

Innovative and improved Drug Development Tools (DDTs) can help streamline the drug development process, improve the chances for clinical trial success, and yield more information about a treatment and/or disease. DDTs include, but are not limited to, biomarkers, clinical outcome assessments, and animal models. Refer to DDTs Qualification Programs at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/default.htm for additional information.

In the Federal Register of January 7, 2014 (79 FR 831), FDA announced the availability of a final guidance for industry entitled “Qualification Process for Drug Development ‘Tools’ that described the process that would be used to qualify DDTs and to make new DDT qualification recommendations available on FDA’s Web site at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm. The current guidance is an attachment to that final guidance.

CDER has initiated this formal qualification process to work with developers of these biomarker DDTs to guide them as they refine and evaluate DDTs for use in the regulatory context. Once qualified, biomarker DDTs will be publicly available for use in any drug development program for the qualified COU. As described in the January 2014 guidance, biomarker DDTs should be developed and reviewed using this process. For more information on FDA’s DDTs Qualification Programs, refer to the following Web page: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/default.htm.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking for the use of Galactomannan detection in serum and/or BAL fluid as the sole microbiological criterion to classify patients as having probable IA for enrollment in clinical trials. 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 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 312.30, 21 CFR 314.50(d)(5), and 21 CFR 314.126(b)(6) have been approved under OMB control numbers 0910–0001 and 0910–0014.

III. 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.

IV. Reference

The following reference is on display in the Division of Dockets Management (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at http://www.regulations.gov.


Dated: November 4, 2015.

Leslie Kux,
Associate Commissioner for Policy.

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The labeling requirements of section 403(y) of the FD&C Act became effective on December 22, 2007, although we exercised enforcement discretion until September 30, 2010, to enable all firms to meet the labeling requirements for dietary supplements. At this time, therefore, we expect that all labels required to include the domestic address or telephone number issued in section 403(y) have been revised accordingly. Thus our current burden estimate for this information collection applies only to new product labels.

In row 1 of Table 1 we estimate the total annual hourly burden necessary to comply with the requirement under section 403(y) of the FD&C Act (21 U.S.C. 343(y)) to be 1,112 hours. Using historical A.C. Nielsen Sales Scanner Data, we estimate the number of dietary supplement SKUs for which product sales are greater than zero to be 55,600. Assuming that the flow of new products is 10 percent per year, then each year an additional 5,560 new dietary supplement products are projected to enter the market. Estimating that there are 1,700 dietary supplement manufacturers, re-packagers, re-labelers, and holders of dietary supplements subject to the information collection requirement (using the figure 1,460 as