TABLE 2—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN: CALORIE CONTENT [1]—Continued

Type of respondent	Number of respondents	Annual frequency per disclosure	Total annual disclosures	Hours per disclosure	Total hours
Other Chains	33,114	1	33,114	2	66,228
Total Initial Hours					964,348
New SRFE Outlets	600	2	1,200	2	2,400
Vending (Ongoing)	5,000	56,000	280,000,000	0.05	14,000,000
Vending (Growth)	5,000	140	700,000	0.05	35,000
Total Recurring Hours					14,037,400

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

Burdens for Chain Vending Machine Operators

Because almost all vending machines sell food that is previously manufactured and packaged, calorie analysis and production of calorie analysis displays will be most efficiently done at the manufacturer level instead of the operator level. Furthermore, most vended foods are subject to NLEA, which means that calorie content is already collected. A likely scenario for response to vending machine labeling is that food manufacturers include a set of calorie label stickers in each case of product. This would be efficient both because most manufacturers will already have the calorie information available, and because economies of scale exist for the manufacturer. In this case, vending machine operators will not need to keep a record of calorie content. Instead, the burden for most operators will be limited to that of administering records and passing the existing information on to consumers.

FDA estimates that there are approximately 300,000 beverage machines that sell unpackaged products. The manufacturer of the ingredients to these foods (hot coffee drinks and sodas) would not necessarily have calorie information if the products were not subject to NLEA in some form. There are likely a limited number of manufacturers of the inputs to the beverage machines. For the purposes of this document, FDA estimates that there are 10 manufacturers serving these machines, and 20 drinks per manufacturer, so that approximately 200 drinks would need to have calorie analysis. The cost of this calorie analysis will be included in the capital costs in the following paragraphs. FDA estimates that the recordkeeping burden for these firms is half that for restaurants, or two hours per item. If there are 600 firms using beverage dispensers, then the hourly burden for recordkeeping is 24,000 hours (= 600 firms × 20 items/firm × 2 hours/item).

FDA believes that the set of items sold in these dispensary machines is approximately constant. If there is .5 percent growth in the number of firms, then approximately three new firms will become covered in this market in a given year. The burden associated with these three firms would be 120 hours (= 3 firms × 20 items/firm × 2 hours/item). This amount is given in eighth row of table 1 of this document.

The third party reporting for chain vending machine operators is the time necessary to install calorie displays on their vending machines. Because there is wide variation in the kinds of vending machines used—in materials, display, mechanism—there will likely be a variety of solutions. On the high end, a calorie display that is integrated with the graphics on the machine may cost several hundred dollars or more. On the low end, a set of calorie stickers affixed to the front of the machine would cost at most a few dollars per machine. Given the low margins in the vending machine industry, and given that nearly all of the regulated operators will be small businesses, FDA believes that almost all operators will, at least initially, choose the sticker option. In the long run, the manufacturers of vending machines, and the larger vending machine operators, such as the soft drink companies, may use the more integrated, and thus expensive, solution.

FDA tentatively estimates a recurring hourly burden of 1 hour per machine, 2 times per year to install the displays. If there are an average of 20 items per machine, then the burden per response is .05 hours (= 1 hours/machine/20 items/machine).This will be the time necessary to decide where to put the displays on the machine, and to sort, remove and affix calorie stickers. FDA expects the stickers to have a relatively short life, and the mix of product in a machine to change over time.

FDA estimates approximately 7 million machines are serviced by 5,000 operators, for an average number of machines per operator of 1,400 machines. If each machine has 20 items, then the average number of responses per operator is 28,000. Given that stickers will likely need to be replaced twice per year on average, this number of responses doubles, to 56,000 responses per operator. The total recurring hours needed for third party display is then 14 million hours (= 5000 firms × 1,400 machines/firm x 20 displays/machine × .05 hours/display × 2). This amount is recurring in every year, and is given in row 7 of table 2 of this document.

If growth in the vending machine industry is .5 percent, then each of the 5,000 respondents will have an average of 7 additional machines that would need to report calorie content each year. With an average number of items per machine of 20, the number of disclosures per respondent is 140. At .05 hours per response, the hours needed to disclose calorie content on new machines is 35,000 hours per year (= 5000 firms × 7 machines/firm × 20 items/machine × .05 hours/item). This amount is displayed in row 8 of table 2 of this document.

Dated: November 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–28014 Filed 11–4–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0275]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Full-Field Digital Mammography System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Full-Field Digital Mammography System." This guidance document describes a means by which a full-field digital mammography (FFDM) system may comply with special controls that apply to these class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify these device types from class III into class II (special controls).

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Full-Field Digital Mammography System" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, Bldg. 66, rm. 4613, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 301–847–8149. *See* the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the 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:

Mary Pastel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G304, Silver Spring, MD 20993–0002, 301–796–6887; or

Kyle J. Myers, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, rm. 3118, Silver Spring, MD 20993–0002, 301–796–2533.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 30, 2008 (73 FR 31040), FDA issued a proposed rule to reclassify an FFDM system from class III (premarket approval) into class II (special controls). Also, in the **Federal Register** of May 30, 2008 (73 FR 31128), FDA announced the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Full-Field Digital Mammography System," which would serve as a special control for the device. The comment period on the proposed rule closed on August 28, 2008.

Following publication of the draft guidance, FDA received a number of comments. We are responding to comments concerning the guidance in this document. We are addressing comments concerning the classification regulation in the preamble to the final rule that is publishing elsewhere in this issue of the **Federal Register**.

We reviewed the comments and took their suggestions into consideration in revising this guidance. The general changes we made to the guidance in response to the comments included: (1) Changing the risk of "incorrect patient positioning" to "inadequate breast coverage"; (2) clarifying when different data are needed for integrated FFDM systems versus detector-only type FFDM systems; (3) revising the listed device description requirements for detector only systems; (4) revising the guidance to consistently use the term "legally marketed (predicate) FFDM device"; (5) revising the footnote referring to part 900 (21 CFR part 900), incorporating a tiered approach to reviewing FFDM devices; and (6) placing greater emphasis on laboratory testing. The changes we made to the clinical aspects of the guidance in response to the comments included: (1) Making the suggested measures less burdensome while providing reasonable assurance of safety and effectiveness and (2) removing, in some cases, suggested measures entirely when we believed that our concerns could be addressed by other measures that we had suggested. The changes we made to the technical aspects of the guidance in response to the comments included: (1) Removing the request for description and specifications of the display from the device description section; (2) removing the request for the life of the detector and the criteria for replacement and recognizing, in the section on "Repeated Exposure Test," international standards (International Electrotechnical Commission) IEC 62220–1–2 and (Final Draft International Standard) FDIS IEC 61223–3–2 in addition to the test recommended in Addendum on Digital Mammography: The European Protocol for the Quality Control of the Physical and Technical Aspects of Mammography Screening, version 1.0, November 2003; (3) removing the clause "whether their [the detector defects] location overlaps the imaged breast" and graphical map recommendation and replacing it in the section now called "Flat Field Correction and Pixel Defects" with the following components: "the number, spatial distribution (single pixels, lines, blocks), and types (dead pixel, sensitivity or offset out of acceptable range) of pixel defects allowed and the rationale for selecting these criteria; and the methods of compensation for these defects"; (4) rewording the "Automatic Exposure Control Performance" section to ask for data based on tissue thickness only rather than preselected kilovolt peak, making it clear that the sponsor should only provide evaluation results for each available Automatic Exposure Control mode, and removing contrast testing; (5) replacing the request for "Bucky factor" with a request for grid ratio, primary transmission, selectivity, and contrast improvement factor; (6) revising section 8 entitled "Physical Laboratory Testing, Breast Compression System" to follow the Mammography Quality Standards Act (MQSA) guidance for compression force, requesting the manufacturer to specify the minimum and maximum powered compressive force for their device and the reasons for choosing the limits, and removing references to accuracy and limits; (7) revising the "Noise Analysis" and "Physical Measurements" portion of the guidance to reference International Standard IEC 62220–1–2, section 6.3.2; (8) revising the "Signal-to-Noise Ratio Transfer—DQE" to reference International Standard IEC 62220–1–2; (9) revising the introduction to the "Physical Laboratory Testing" section to allow greater latitude in choice and be less prescriptive; (10) removing references to MQSA qualifications from the "Phantom Testing" section; and (11) revising the section addressing patient radiation dose to remove reference to the "standard breast" and clarifying that FDA seeks phantom data only and reduce the range of breast sizes from 2 to 8 centimeters (cm) to 2 to 6 cm.

II. Significance of Special Controls Guidance

FDA believes that adherence to the recommendations described in this guidance document, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the FFDM system classified under § 892.1715 (21 CFR 892.1715). In order to be classified as a class II device under § 892.1715, a new FFDM system must comply with the

requirements of special controls; manufacturers must address the issues requiring special controls as identified in the guidance document, either by following the recommendations in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive "Class II Special Controls Guidance Document: Full-Field Digital Mammography System," you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1616 to identify the guidance you are requesting.

IV. 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 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 900 have been approved under OMB control number 0910–0309.

V. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: November 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–28004 Filed 11–4–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, Pharmacokinetic Research in Pediatric HIV/TB Co-Infection.

Date: December 2, 2010.

Time: 9 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Anne Krey, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01 Bethesda, MD 20892. 301–435–6908. *kreya@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 1, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–28081 Filed 11–4–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development, Special Emphasis Panel, Williams Syndrome.

Date: November 30, 2010.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Blvd., Rockville, MD (Teleconference).

Contact Person: Norman Chang, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301–496–1485, *changn@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 1, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–28079 Filed 11–4–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as