II. Significance of Guidance

FDA is issuing this draft guidance document consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.'' 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

This draft guidance contains proposed collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). As required by the PRA, FDA has published an analysis of, among others, the information collection concerning the submission of tobacco product establishment registration and product listing information (74 FR 45219, September 1, 2009, as corrected by 74 FR 47257, September 15, 2009) and will submit them for OMB approval.

V. Electronic Access

An electronic version of the guidance document is available on the Internet at *http://www.regulations.gov* and *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: October 15, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25235 Filed 10–16–09; 11:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0503]

Draft Guidances for Industry and Food and Drug Administration Staff; Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification [510(k)] Submissions and Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two related draft guidance documents. One is a draft guidance entitled, ''Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification [510(k)] Submissions'' (''CADe 510(k) draft guidance''). This draft guidance provides recommendations regarding premarket notification (510(k)) submissions of certain computer-assisted detection (CADe) devices applied to radiology images and radiology device data. The second draft guidance is entitled, ''Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions'' (''CADe clinical performance assessment draft guidance''). This draft guidance provides recommendations on how to design and conduct clinical performance studies for CADe devices applied to radiology images and radiology device data. These studies may be part of a premarket submission to FDA, whether it is a 510(k) submission, an application for premarket approval (PMA), an application for a humanitarian device exemption (HDE), or an application for an investigational device exemption (IDE). These draft guidances are not final nor are they 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 on these draft guidances before it begins work on the final versions of these guidances, submit written or electronic comments on the draft guidances by January 19, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification [510(k)] Submissions'' or the draft guidance document entitled ''Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., WO66–4613, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to these draft guidances.

Submit written comments concerning either of these draft guidances and the questions found in the supplementary information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document. Please include your rationale and/or scientific justification with your comments.

FOR FURTHER INFORMATION CONTACT: Nicholas Petrick, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., White Oak Bldg. 62, rm. 4116, Silver Spring, MD 20993, 301–796–2563, and Joyce Whang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., White Oak Bldg. 66, rm. G318, Silver Spring, MD 20993.

SUPPLEMENTARY INFORMATION:

I. Background

CADe devices are computerized systems that incorporate pattern recognition and data analysis capabilities (i.e., combine values, measurements, or features extracted from the patient radiological data) intended to identify, mark, highlight, or in any other manner direct attention to portions of an image, or aspects of radiology device data, that may reveal abnormalities during interpretation of

patient radiology images or patient radiology device data by the intended user (i.e., a physician or other health care professional). In drafting these documents, we considered the recommendations made during the Radiological Devices Panel on March 4 through 5, 2008. Further information on this public advisory committee meeting, including panel transcripts, can be found at: *http://www.fda.gov/ohrms/dockets/ac/cdrh08.html#radiology*.

The CADe 510(k) draft guidance provides recommendations on documentation and performance testing to be part of a 510(k) submission for Class II CADe devices applied to radiology images and radiology device data. The CADe clinical performance assessment draft guidance provides recommendations regarding clinical performance studies for both Class II and Class III CADe devices applied to radiology images and radiology device data.

II. Frequently Asked Questions

The agency anticipates including a section containing frequently asked questions (FAQs) in each of the guidances to further clarify the agency's recommendations regarding premarket notification (510(k)) submissions of certain computer-assisted detection (CADe) devices applied to radiology images and radiology, and on how to design and conduct clinical performance studies for CADe devices applied to radiology images and radiology device data. The agency is requesting public comment on the proposed sample questions provided in this document. Suggestions for additional questions and answers that are not included below but that may be helpful in understanding the guidances are also encouraged. The public comments will allow the agency to further refine the guidance and develop a FAQ section to communicate the recommended level of evidence for different premarket submissions. The agency also wants to ensure that these guidances adequately address these anticipated questions. The agency may adjust, add or delete questions based on received comments.

The first group of draft sample questions (Q1–Q7) has been developed to provide context to the principles discussed in the CADe 510(k) draft guidance. They may help in preparing a Premarket Notification [510(k)] Submission for your CADe device. Please comment on the following questions and what you believe would be the expectation of the agency based on the issues presented in the CADe 510(k) draft guidance.

Q1: Our CT CADe device is intended to be used on a variety of CT devices. Should any clinical trials we perform include every unit with which the CT CADe device is intended to be used?

Q2: Our CADe device is designed to detect lung nodules. Should we power our standalone performance assessment so that statistically significant results can be obtained for the clinically relevant subgroups of lesions, for example, nodules near the mediastinum versus the peripheral lung fields?

Q3: We have an already cleared CADe device and have updated one of its algorithms. Should we perform another clinical performance assessment (i.e., a reader study)?

Q4: We have a new CADe device and have done standalone testing comparing it to an already cleared CADe device. Our new CADe identified additional cancers and had fewer false positive marks than the cleared device but ours missed some of the cancers detected by the cleared device. Should we perform a clinical performance assessment?

Q5: We have an already cleared CADe device and have changed the prompt format (e.g., masses are now marked with a circle rather than an arrow). Should we perform another clinical performance assessment?

Q6: In a 510(k), can I reuse the test dataset that supported clearance of the predicate CADe device and if so what are the constraints on this reuse?

Q7: Our colon CADe device can be used for both 2D and 3D interpretation. Should we perform clinical tests using both interpretation modes?

The second set of draft sample questions (Q8–Q11) has been developed to provide context to the principles discussed in the CADe clinical performance assessment draft guidance. They may help in developing and conducting a clinical performance assessment of your CADe device to support clearance or approval. Again, please comment on these questions and what you believe would be the expectation of the agency based on the issues presented in the CADe clinical performance assessment draft guidance.

Q8: The guidance calls for the trial readers to be ''representative of the intended population of clinical users.'' Can you give some examples and should the number of readers in each of the subgroups be proportional to the numbers in the population of clinical users?

Q9: We have a new breast CADe device and would like to market it for use with all legally marketed Full Field Digital Mammography (FFDM). Should we perform reader studies with each legally marketed FFDM?

Q10: We have a breast CADe device approved for use with a specific legally marketed Full Field Digital Mammography (FFDM) based on a robust MRMC study. We would like to market it for use with an additional legally marketed FFDM. Should we perform a clinical performance assessment (i.e., reader study) to assess the CADe for use with the new FFDM or is standalone performance data enough to demonstrate comparable results based on the specifications of the device?

Q11: We have improved our legally marketed CADe device and will be submitting a new 510(k) for the upgraded version. Is image reading without CADe a suitable control arm against which to compare the upgraded CADe device?

The agency is seeking input to the previous sample questions and suggestions on additional questions so that it can further refine the guidance and develop a FAQ section to communicate the recommended level of evidence for different premarket submissions. Your input would allow us to consider multiple viewpoints of what is the adequacy of evidence for these devices.

III. Significance of Guidance

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidances, when finalized, will represent, respectively, the agency's current thinking on '' Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification [510(k)] Submissions'' and on ''Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions.'' The guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. Alternative approaches may be used if such approaches satisfy the requirements of the applicable statute and regulations.

IV. Electronic Access

Persons interested in obtaining a copy of either draft guidance may do so by using the Internet. To receive ''Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification [510(k)] Submissions,'' 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 1697 to identify the draft guidance you are requesting. To receive ''Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions,'' 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 1698 to identify the draft guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.regulations.gov*.

V. Paperwork Reduction Act of 1995

These draft guidances contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520) (the PRA). The collections of information addressed in these draft guidance documents have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB No. 0910–0120), premarket approval applications (21 CFR part 814, OMB No. 0910–0231), investigational device exemptions (21 CFR part 812, OMB No. 0910–0078), and humanitarian use devices (21 CFR part 814, OMB No. 0910–0332). The labeling provisions addressed in the ''Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data—Premarket Notification [510(k)] Submissions'' draft guidance have been approved by OMB under OMB No. 0910–0485.

VI. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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: October 15, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25233 Filed 10–20–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0473]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the special controls guidance document entitled ''Class II Special Controls Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems.'' This guidance document describes a means by which cardiac allograft gene expression profiling test systems may comply with the requirement of special controls for class II devices. It includes recommendations for validation of performance characteristics and recommendations for product labeling. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule codifying the classification of cardiac allograft gene expression profiling test systems into class II (special controls), and establishing this guidance document as the special control for this device.

DATES: Submit 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: Cardiac Allograft Gene Expression Profiling Test Systems'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments to *http://www.regulations.gov*. Submit written comments concerning this guidance 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: Kellie B. Kelm, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5625, Silver Spring, MD 20993, 301–796–6145.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule codifying the classification of cardiac allograft gene expression profiling test systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)) and establishing this guidance document as the special control for cardiac allograft gene expression profiling test systems classified under that regulation. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Under this authority, on August 26, 2008, FDA by order classified into class II, subject to this special control guidance document, the XDx AlloMap Test.