DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration

Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 048

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications to the list of recognized standards. This publication, entitled “Modifications to the List of Recognized Standards, Recognition List Number: 048” (Recognition List Number: 048), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements as identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2004–N–0451 for “Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 048.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 048.

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

I. Background


In the Federal Register notice of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled “Recognition and Use of Consensus Standards.” The notice described how FDA would implement its standard recognition program and provided the initial list of recognized standards. The guidance was updated in September 2007 and is available at https://www.regulations.gov/.
standards recognized by FDA. The Agency maintains hypertext markup language (HTML) and portable document format (PDF) versions of the list of FDA Recognized Consensus Standards. Additional information on the Agency’s standards program is available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm.

In table 1, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 048. FDA lists modifications the Agency is making that involve the initial addition of standards not previously recognized by FDA.

### III. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. FDA will be incorporating the modifications described in this notice into the database and, upon publication in the Federal Register, this recognition of consensus standards will be effective. FDA will be announcing additional modifications and revisions to the list of recognized consensus standards, as needed, in the Federal Register once a year, or more often if necessary.

### IV. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to CDRHStandardsStaff@fda.hhs.gov. To be considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and electronic or mailing address of the requestor, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2017–26043 Filed 12–1–17; 8:45 am]

BILLING CODE 4164–01–P

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–N–0192]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing and Maintaining Lists of United States Manufacturers/Processors With Interest in Exporting Center for Food Safety and Applied Nutrition-Regulated Products to China

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

---

### II. Listing of New Entries, Recognition List Number: 048

<table>
<thead>
<tr>
<th>Recognition No.</th>
<th>Title of standard ¹</th>
<th>Reference No. and date</th>
</tr>
</thead>
</table>

A. Radiology

<table>
<thead>
<tr>
<th>Recognition No.</th>
<th>Title of standard ¹</th>
<th>Reference No. and date</th>
</tr>
</thead>
</table>

B. Software/Informatics

<table>
<thead>
<tr>
<th>Recognition No.</th>
<th>Title of standard ¹</th>
<th>Reference No. and date</th>
</tr>
</thead>
</table>

### ¹ All standard titles in this table conform to the style requirements of the respective organizations.