specific types of irrigation valves and accessories when used with flexible gastrointestinal endoscopes, clarify terminology used to describe these devices, and outline strategies to mitigate the risk of cross-contamination between patients. This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 20, 2015.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 Submit written requests for a single hard copy of the draft guidance document entitled ''Mitigating the Risk of Cross-Contamination From Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes'' 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Submit electronic comments on the draft guidance to *http://www.regulations.gov*.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: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993–0002, 301–796–6527.

SUPPLEMENTARY INFORMATION:

I. Background

During colonoscopy or esophagogastroduodenoscopy, clinicians often use a water bottle to supply irrigation for the procedure. Clinicians typically use a single water bottle for multiple patients without reprocessing the water bottle between patients. This practice raises the risk of cross-contamination between patients, because the water bottle and associated tubing/connectors can become contaminated with blood or stool that travels up through the endoscope channels and tubing (a phenomenon referred to as ''backflow''). FDA has received reports of backflow from colonoscope irrigation channels into the water bottle and tubing when the irrigation channel did not have a backflow-prevention mechanism in place.

This draft guidance document, when finalized, will: (1) Highlight the cross-contamination risk associated with specific types of irrigation valves and accessories when used with flexible gastrointestinal endoscopes; (2) clarify terminology used to describe these devices; and (3) and outline strategies to mitigate the risk of cross-contamination between patients. These strategies will include recommendations on device design and appropriate labeling.

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 mitigating the risk of cross-contamination from valves and accessories used for irrigation through flexible gastrointestinal endoscopes. 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 ''Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400054 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 (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 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 and 809 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: January 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–00755 Filed 1–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1039]

General Wellness: Policy for Low Risk 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 the draft guidance entitled ''General Wellness: Policy for Low Risk Devices.'' FDA is issuing this draft guidance to provide clarity to industry and FDA staff on the Center for Devices and Radiological Health's (CDRH's) compliance policy for low risk products that promote a healthy lifestyle (general wellness products). 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 on 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 April 20, 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 ''General Wellness: Policy for Low Risk 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: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5449, Silver Spring, MD 20993–0002, 301–796–8589.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this draft guidance to provide clarity to industry and FDA staff on CDRH's compliance policy for low-risk products that promote a healthy lifestyle (general wellness products). CDRH does not intend to examine low-risk general wellness products, as discussed in this guidance, to determine whether they are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(h)), or, if they are devices, whether they comply with the FD&C Act's regulatory requirements for devices. This guidance does not apply to products regulated by other FDA Centers (*e.g.,* drugs, biologics, dietary supplements, foods, or cosmetics) or to combination products, including those regulated by CDRH. By clarifying CDRH's policy on general wellness products, we hope to improve the predictability, consistency, and transparency on CDRH's regulation of these products.

For purposes of the guidance, CDRH defines ''general wellness products'' as products which meet the following factors: (1) Are intended for only general wellness use, as defined in this guidance and (2) present a very low risk to users' safety. General wellness products can include exercise equipment, audio recordings, mobile apps, video games, and other products that are typically available from retail establishments (including online retailers and distributors that offer mobile apps to be directly downloaded), when consistent with the two factors above.

The scope of the guidance is limited to certain products that have either: (1) An intended use that relates to maintaining or encouraging a general state of health or a healthy activity or (2) an intended use that associates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions. For the first category of general wellness products, the intended use do not include any reference or connection to diseases or conditions and only relate to weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function. For the second category of general wellness products, the product is intended to promote, track, and/or encourage choice(s), which, as part of a healthy lifestyle, may either help to reduce the risk of, or help living well with, chronic diseases or conditions where it is well understood that the healthy lifestyle choice(s) may reduce the risk or impact of a chronic disease or condition.

The general wellness policy does not extend to devices that present inherent risks to a user's safety. The guidance sets out factors we will consider to identify a device as low risk. If the product is invasive, involves an intervention or technology that may pose a risk to a user's safety if device controls are not applied (such as risks from lasers, radiation exposure, or implants), raises novel questions of usability, or raises questions of biocompatibility, then the device is not covered by this guidance.

We welcome comments on all aspects of this draft guidance. We are particularly interested in comments regarding CDRH's proposed list of general wellness intended uses that relate to maintaining or encouraging a general state of health or a healthy activity. Please comment on the current list as well as other intended uses regarding sustaining or offering general improvement to conditions and functions associated with a general state of health that do not make any reference to diseases or conditions that CDRH should consider including in the list.

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 proposed approach on general wellness products. 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 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*. Persons unable to download an electronic copy of ''General Wellness: Policy for Low Risk 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 1830 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 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807 (registration and listing and premarket notification (510(k))) have been approved under OMB control numbers 0910–0625 and 0910–0120, respectively; the collections of information in 21 CFR part 801 and 21 CFR 809.10 (labeling) have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 820 (good manufacturing practice requirements as set forth in the quality system regulation) have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 803 (medical device reporting (MDR) requirements) have been approved under OMB control number 0910–0437.

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: January 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–00756 Filed 1–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 79 FR 75164–75165 dated December 17, 2014).

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA). Specifically, this notice: (1) Establishes the Office of Human Resources (RB6); (2) establishes the Division of HR Operations (RB61), Division of Workforce Relations (RB62), and the Division of HR Policy and Technology (RB63), within the Office of Human Resources (RB6); (3) transfers the Division of Workforce Development (RB64) to the newly established Office of Human Resources (RB6); (4) abolishes the Division of Human Resources Management (RB42); (5) renames the Office of Management to the Office of Administrative Management (RB4); (6) renames the Division of Policy and Information Coordination to the Division of the Executive Secretariat (RB41); (7) establishes the Division of Executive Office Services (RB45), Division of Logistics and Support (RB46), and the Division of Security Services (RB47), within the Office of Administrative Management (RB4); (8) abolishes the Division of Management Services (RB43); (9) renames the Division of Contract Services for Primary Care, Health Systems and Clinician Recruitment and Retention to the Division of Technology and Enterprise Solutions (RB3A), and the Division of Contract Services for Maternal and Child Health and Administrative Support Offices to the Division of Primary Care and Health Infrastructure Support (RB3B), and the Division of Contract Services for HIV/AIDS, Health Professions, Rural Health and Grants Management to the Division of Population-Based Support (RB3C), within the Office of Acquisitions Management and Policy (RB3); (10) establishes the Division of Policy and Data Analysis (RB33) and the Division of Financial Support Services (RB34) within the Office of Acquisitions Management and Policy (RB3); (11) abolishes the Contract Administration Division (RB38) within the Office of Acquisitions Management and Policy (RB3); (12) renames the Division of IT Operational Support Services to the Division of End User Support (RB58), within the Office of Information Technology (RB5); (13) establishes the Division of Infrastructure Services (RB57), within the Office of Information Technology (RB5); and (14) abolishes the Division of IT Management Support Services (RB57), the Division of Web Support and Collaboration Services (RB59), and the Division of IT Security and Records Management (RB5R) within the Office of Information Technology (RB5).

Chapter RB—Office of Operations

Section RB–00, Mission

To improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs.

Section RB–10, Organization

Delete the organization for the Office of Operations (RB) in its entirety and replace with the following:

The Office of Operations (RB) is headed by the Chief Operating Officer, who reports directly to the Administrator, Health Resources and Services Administration. The Office of Operations includes the following components:

(1) Office of Operations (RB);

(2) Office of Budget (RB1);

a. Division of Budget Formulation and Presentation (RB11);

b. Division of Budget Execution and Management (RB12);

c. Division of Program Budget Services (RB13);

(3) Office of Financial Policy and Controls (RB2);

a. Division of Internal Controls (RB21);

b. Division of Financial Policy and Analysis (RB22);

(4) Office of Acquisitions Management and Policy (RB3);

a. Division of Technology and Enterprise Solutions (RB3A);

b. Division of Primary Care and Health Infrastructure Support (RB3B);

c. Division of Population-Based Support (RB3C);

d. Division of Policy and Data Analysis (RB33);

e. Division of Financial Support Services (RB34);

(5) Office of Administrative Management (RB4);

a. Division of the Executive Secretariat (RB41);

b. Division of Executive Office Services (RB45);

c. Division of Logistics and Support (RB46);

d. Division of Security Services (RB47);

(6) Office of Information Technology (RB5);

a. Division of Capital Planning, Architecture and Project Management (RB52);

b. Division of Data and Information Services (RB55);

c. Division of Enterprise Solutions and Applications Management (RB56);

d. Division of Infrastructure Services (RB57);

e. Division of End User Support (RB58); and

(7) Office of Human Resources (RB6);

a. Division of HR Operations (RB61);

b. Division of Workforce Relations (RB62);

c. Division of HR Policy and Technology (RB63);

d. Division of Workforce Development (RB64).

Section RB–20, Functions

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA). Specifically, this notice: (1) Transfers the human resources function from the Office of Management to the Office of Human Resources (RB6); (2) transfers the emergency operations function from the Office of Information Technology (RB5) to the Office of Administrative Management (RB4); (3) transfers the functions from the Division of Management Services to the Division of Executive Office Services (RB45), Division of Logistics and Support (RB46), and the Division of Security Services (RB47), within the Office of Administrative Management (RB4); (4) transfers the function of the Contract Administration Division to the Division of Policy and Data Analysis (RB33), and the Division of Financial Support Services (RB34), within the Office of Acquisitions Management and Policy (RB3); (5) transfers the functions of the Division of IT Management Support