

with the Agency's intention for further integration to maximize the strengths of the QIO program and PfP HENs to sustain and expand current national reductions in in-patient harm and 30-day readmissions. The alignment of the two programs permits the systematic use of innovative patient safety practices at a national scale.

Under this initiative, CMS has awarded multiple contracts to Hospital Improvement Innovation Networks (HIINs), formerly known as HENs, to engage the hospital, provider, and broader caregiver communities to implement well-tested and measured best practices. The end result of the overall initiative is the anticipated reduction in preventable hospital-based harm and readmissions for patients.

The PfP initiative is a public-private partnership dedicated to the improvement of health care quality, safety, and affordability. CMS, working with hospitals, providers, and the broader caregiver community, aims to implement and disseminate best practices on a national scale to reduce hospital acquired conditions (HACs) and all-cause readmissions. Through the PfP model, which was initiated in April 2011, CMS fostered rapid learning among a nationwide community of practice, resulting in major strides in patient safety and engagement by patients and families.

A mixed methods approach to answering the PfP HIIN evaluation questions includes three primary data collection activities, as follows: Hospital Survey on Prevention of Adverse Events and Reduction of Readmissions, HIIN Data Quality Assurance (QA) Survey and Qualitative Discussions with HIIN leaders and Other Support Contractors. The data collected will provide us feedback to focus efforts to improve the effectiveness and efficiency of the HIIN initiative. As we draft future HIIN and QIO contracts, information from hospitals about HIIN influence on their care processes will be used together with follow-up input from stakeholders about the survey results. *Form Number:* CMS-10656 (OMB Control Number: 0938-NEW); *Frequency:* Annually; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 835; *Total Annual Responses:* 854; *Total Annual Hours:* 392. (For policy questions regarding this collection contact Israel Cross at 410-786-0619.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Report of a Hospital Death Associated with Restraint or Seclusion; *Use:* The

regulation that was published on May, 16, 2012 (77 FR 29074) included a reduction in the reporting requirement related to hospital deaths associated with the use of restraint or seclusion, § 482.13(g). Hospitals must use Form CMS-10455 to report those deaths associated with restraint and/or seclusion directly to the Centers for Medicare & Medicaid Services (CMS) Regional Office (RO). This requirement also applies to rehabilitation or psychiatric distinct part units (DPUs) in Critical Access Hospitals (CAHs). The RO must provide hospitals with instructions for submitting the form fax and/or email, based on RO preference. Hospitals are no longer required to report to CMS those deaths where there was no use of seclusion and the only restraint was 2-point soft wrist restraints beginning in May 9, 2014. This reporting requirement change resulted in no necessary edits to the form CMS-10455 as soft wrist restraints may be used in combination with other types of restraints. It was estimated that this would reduce the volume of reports that must be submitted by 90 percent for hospitals. In addition, the final rule replaced the previous requirement for reporting via telephone to CMS, which proved to be cumbersome for both CMS and hospitals, with a requirement that allows submission of reports via telephone, facsimile or electronically, as determined by CMS.

Form CMS-10455 is being revised in order to obtain the necessary information for the ROs to make a determination whether or not to authorize an on-site investigation related to the details surrounding the death of individuals associated with restraint and/or seclusion. *Form Number:* CMS-10455 (OMB control number: 0938-1210); *Frequency:* Occasionally; *Affected Public:* Private Sector; *Number of Respondents:* 6,389; *Number of Responses:* 6,389; *Total Annual Hours:* 2,619. (For policy questions regarding this collection contact Karina Meushaw at 410-786-1000.)

Dated: November 1, 2017.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-D-0529]

#### Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery." The guidance is intended to promote the safe use of nonprescription (also referred to as over-the-counter or OTC) aspirin drug products by encouraging drug manufacturers, packagers, and labelers marketing aspirin drug products with cardiovascular-related imagery to include a statement that reminds consumers to talk to their health care provider before using aspirin for their heart.

**DATES:** The announcement of the guidance is published in the **Federal Register** on November 7, 2017.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you

do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### 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, Rm. 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.”

*Instructions:* All submissions received must include the Docket No. FDA-2012-D-0529 for “Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery; Guidance for Industry.” 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.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION”. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/>

[fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf](https://www.fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf).

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Emily Baker, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51 Rm. 5203, Silver Spring, MD 20993-0002, 301-796-7524.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for industry entitled “Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery.” Aspirin is a common active ingredient in many prescription and OTC drug products. Most OTC aspirin drug products are currently marketed pursuant to the Tentative Final Monograph (TFM) for Internal Analgesic, Antipyretic, and Antirheumatic (IAAA) Drug Products (53 FR 46204, November 16, 1988) for the temporary relief of minor aches and pains associated with a cold, headache, backache, toothache, premenstrual and menstrual cramps, minor pain of arthritis, and reduction in fever.

In addition to the OTC conditions of use in the IAAA TFM, FDA regulations at § 343.80 (21 CFR 343.80) also contain professional labeling about cardiovascular uses of aspirin directed at health care practitioners (63 FR 56802, October 23, 1998). After publication of the professional labeling regulation for aspirin, some OTC aspirin labels were modified to include cardiovascular-related imagery (e.g., heart image, electrocardiography

graphic, stethoscope around a heart image). However, the final rule for IAAA products at § 343.80 authorizes labeling for cardiovascular events only in professional labeling directed to health care professionals.

Because of the potential side effects associated with long-term aspirin therapy, FDA recommends that any cardiovascular-related imagery on OTC aspirin labels be accompanied by a statement that reminds consumers to talk to their health care provider before using aspirin for the professional indication of secondary prevention of cardiovascular events. Therefore, this guidance provides that FDA does not intend to take action against manufacturers of single-ingredient aspirin, buffered aspirin, and aspirin in combination with an antacid, marketed pursuant to the TFM for IAAA Drug Products because the product label includes cardiovascular-related imagery (e.g., heart image, electrocardiography graphic, stethoscope around a heart image) if the label also includes language as described in the guidance recommending that patients talk to a health care professional before taking aspirin for cardiovascular uses and the product is otherwise marketed in accordance with the TFM.

In the **Federal Register** of January 11, 2017 (82 FR 3335), FDA published a draft guidance entitled “Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery; Guidance for Industry.” We have made changes to the guidance in response to comments received and revised the recommended statement to make it more consumer friendly.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery.” 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. This guidance is not subject to Executive Order 12866.

##### **II. Paperwork Reduction Act of 1995**

The recommendations in this guidance are not subject to review by the Office of Management and Budget because they do not constitute a “collection of information” under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Rather, the labeling statements are a “public disclosure of

information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)).

### III. Electronic Access

Persons with access to the internet may obtain the document at either <https://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: November 2, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-1129]

#### Medical Devices; Exemptions From Premarket Notification: Class II Devices; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing its intent to exempt a list of class II devices from premarket notification requirements, subject to certain limitations. The Agency has determined that, based on established factors, these devices no longer require premarket notification to provide reasonable assurance of safety and effectiveness. FDA is publishing this notice to obtain comments regarding the proposed exemptions, in accordance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

**DATES:** Submit either electronic or written comments on the notice by January 8, 2018.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 8, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of January 8, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### 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, Rm. 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.”

**Instructions:** All submissions received must include the Docket No. FDA-2017-N-1129 for “Medical Devices; Exemptions from Premarket Notification: Class II Devices; Request for Comments.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the

information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Bryce Bennett, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5244, Silver Spring, MD 20993, 301-348-1446, [Gregory.Bennett@fda.hhs.gov](mailto:Gregory.Bennett@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION :

##### I. Statutory Background

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations, 21 CFR part 807 subpart E, require persons who intend to market a new device to submit and obtain clearance of a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is “substantially equivalent” within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Cures Act) (Pub. L. 114-255) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended,