conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A of the FD&C Act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the FD&C Act provides that: ''. . . no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) . . . .'' The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the Nutrition Labeling and Education Act of 1990, Pub. L. 101–535, 104 Stat. 2353, 2364 (1990)). The final rule creates requirements that fall within the scope of section 403A(a) of the FD&C Act.

IX. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA. Final Regulatory Impact Analysis, Regulatory Flexibility Analysis for Final Rule on ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Compliance Dates.'' April 2018. Available from *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses.*
2. Sheahan, M. ''FDA Blog Post.'' *Label Insight.* April 5, 2018. Available at *https://blog.labelinsight.com/growing-new-label-adoption-provides-transparency-for-consumers.*
3. Food and Drug Administration, ''Reference Amounts Customarily Consumed: List of Products for Each Product Category; Guidance for Industry; Availability.'' 83 FR 9000 (March 2, 2018). Guidance available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm535368.htm.*
4. Food and Drug Administration, ''Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition; Guidance for Industry; Availability. '' 83 FR 8997 (March 2, 2018). Guidance available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm528532.htm.*
5. Food and Drug Administration, ''The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products; Draft Guidance for Industry; Availability.'' 83 FR 8953 (March 2, 2018). Guidance available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm595578.htm.*

Dated: April 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–09476 Filed 5–3–18; 8:45 am]

BILLING CODE 4164–01–P2

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2017–N–6216]

General Hospital and Personal Use Devices; Reclassification of Sharps Needle Destruction Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a final order to reclassify the needle destruction device, renaming the device to ''sharps needle destruction device,'' a postamendments class III device (regulated under product code MTV), into class II (special controls), subject to premarket notification. FDA is also identifying the special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is finalizing this reclassification on its own initiative based on new information. The Agency is classifying the device into class II (special controls) to provide a reasonable assurance of safety and effectiveness of the device. This order reclassifies these types of devices from class III to class II and will reduce regulatory burdens on industry because these types of devices will no longer be required to submit a premarket approval application (PMA), but can instead submit a less burdensome premarket notification (510(k)) before marketing their device.

DATES: This order is effective June 4, 2018.

FOR FURTHER INFORMATION CONTACT: Christopher K. Dugard, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2561, Silver Spring, MD 20993, 240–402–6031, *christopher.dugard@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3). Section 513(f)(3) of the FD&C Act provides that FDA acting by order can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available regulatory authority (see *Bell*

v. *Goddard,* 366 F.2d 177, 181 (7th Cir. 1966); *Ethicon, Inc.* v. *FDA,* 762 F. Supp. 382, 388–391 (D.D.C. 1991)) or in light of changes in ''medical science'' (*Upjohn* v. *Finch,* 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the ''new information'' to support reclassification under 513(f)(3) must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, *e.g., General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA,* 766 F.2d 592 (D.C. Cir.1985), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending PMA (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c)). Section 520(h)(4) of the FD&C Act provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device, but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the 510(k) premarket notification requirements, if the Agency determines that premarket notification is not necessary to reasonably assure the safety and effectiveness of the device.

On November 7, 2017, FDA published an order in the **Federal Register** to reclassify the device (82 FR 51585) (the ''proposed order''). The period for public comment on the proposed order closed on January 8, 2018. FDA received and has considered two comments on the proposed order, as discussed in section II.

II. Comments on the Proposed Order and FDA Response

A. Introduction

We received two comments on the proposed order and both comments supported the proposed reclassification. The comments were received from a consumer and a healthcare professional in the drug industry.

We describe and respond to the comments in section B of this section. The order of response to the commenters is purely for organizational purposes and does not signify the comment's value or importance nor the order in which comments were received.

B. Description of Comments and FDA Response

(Comment 1) One commenter discussed the experience of witnessing sharps disposal and was supportive of safe and cost-effective options for sharps disposal due to the potential injury to sanitation works or patients/users with improper disposal of sharps. The commenter was generally supportive of FDA's proposed reclassification. Additionally, the commenter stated that PMA requirements increase the price of these devices and that reclassification increases affordability of the sharps needle destruction devices, while ensuring safety.

(Response 1) FDA agrees with this comment. The Agency believes that reclassification of the sharps needle destruction device will reduce the regulatory burden on manufacturers, which could increase patient access to these devices and potentially reduce accidental needle sticks, while still providing reasonable assurance of safety and effectiveness. Additionally, FDA believes the special controls mitigate workplace hazards associated with sharps needle destruction and ensures proper use of the device.

(Comment 2) One commenter noted that while a PMA for these devices will no longer be required, FDA will still require premarket notification under section 510(k) of the FD&C Act. The commenter stated that in addition to 510(k) requirements, a prescription use restriction, and labeling, the identified special controls will provide reasonable assurance of device safety and effectiveness. The commenter noted that PMAs delay the access of these devices to patients. The commenter concluded that this reclassification may factor in positive outcomes for patient access and safety.

(Response 2) FDA agrees with this comment. The Agency believes that the special controls required in this final order provide a reasonable assurance of safety and effectiveness for these devices. FDA believes it has identified the risks to health (see section V of the proposed order) and that the measures described in this final order will be effective in mitigating the identified probable risks to health. Additionally, by reclassifying these types of devices from class III to class II, this will reduce regulatory burdens on industry because these types of devices will no longer be required to submit a PMA, but can instead submit a less burdensome premarket notification (510(k)) before marketing their device.

III. The Final Order

FDA is adopting its findings under section 513(f)(3) of the FD&C Act, as published in the preamble to the proposed order. FDA is issuing this final order to reclassify needle destruction devices from class III to class II, rename them sharps needle destruction devices, and establish special controls by revising 21 CFR part 880. In this final order, the Agency has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls, provide a reasonable assurance of the safety and effectiveness for sharps needle destruction devices.

FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act under section 510(m) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the devices. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of sharps needle destruction devices, and therefore, this device type is not exempt from premarket notification requirements.

The device is assigned the generic name sharps needle destruction device, and it is identified as a prescription device that is intended to destroy needles or sharps used for medical purposes by incineration or mechanical means.

Under this final order, the sharps needle destruction device is a prescription use device under § 801.109 (21 CFR 801.109). Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of § 801.109 are met (referring to 21 U.S.C. 352(f)(1)). Under 21 CFR 807.81, the device would continue to be subject to 510(k) requirements.

IV. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other 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 part 807, subpart E have been approved under OMB control number 0910–0120 and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.,* as amended) and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 880.6210 to subpart G to read as follows:

§ 880.6210 Sharps needle destruction device.

(a) *Identification.* A sharps needle destruction device is a prescription device that is intended to destroy needles or sharps used for medical purposes by incineration or mechanical means.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Performance testing must demonstrate the following during operation of the device:

(i) The device safely contains or ventilates aerosols or fumes from device operation.

(ii) Excessive heat or sparks are not generated that may injure users or patients.

(iii) Simulated use testing must demonstrate sharps and/or needles are completely destroyed using a range of types and sizes of sharps sufficient to represent actual use.

(iv) Simulated use testing must demonstrate that the device is physically stable on the surface for which it is intended to be mounted to ensure the risk of harm to the patient/user as a result of the device falling is minimized.

(2) Validation of cleaning and disinfection instructions must demonstrate that the device can be safely and effectively reprocessed after use per the recommended cleaning and disinfection protocol in the instructions for use.

(3) Analysis and/or testing must validate electromagnetic compatibility and electrical safety, including the safety of any battery used in the device, under conditions which are consistent with the intended environment of device use.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Labeling must include:

(i) A clear description of the device and its technological features;

(ii) How the device is to be used, including validated cleaning and disinfection instructions;

(iii) Relevant precautions and warnings based on performance and in-use testing to ensure proper use of the device; and

(iv) Instructions to install device in adequately ventilated area and stable area.

Dated: April 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–09434 Filed 5–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2017–0993]

RIN 1625–AA08

Special Local Regulation: Fort Lauderdale Air Show; Atlantic Ocean, Fort Lauderdale, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a recurring special local regulation for certain navigable waters of the Atlantic Ocean east of Fort Lauderdale, Florida beginning at the Port Everglades Inlet and extending north approximately six miles. The special local regulation is necessary to ensure the safety of the public, spectators, vessels, and the marine environment during aerobatic maneuvers conducted by high-speed, low-flying airplanes and high speed vessels performing inside of the regulated area during the Fort Lauderdale Air Show. This special local regulation prohibits persons and non-participant vessels from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Miami or a designated representative.

DATES: This rule is effective May 4, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2017–0993 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Mara J. Brown, Sector Miami Waterways Management Division, U.S. Coast Guard; telephone 305–535–4317, email *Mara.J.Brown@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The City of Fort Lauderdale notified the Coast Guard that it would be hosting the Fort Lauderdale Air Show annually over a Saturday and Sunday during the month of May. The regulated area would cover certain navigable waters of the Atlantic Ocean east of Fort Lauderdale, Florida beginning at Port Everglades Inlet and continuing north for approximately six miles.

In response, on January 25, 2018, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Special Local Regulation: Fort Lauderdale Air Show; Atlantic Ocean, Fort Lauderdale, FL'' (83 FR 3450). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this event. During the comment period that ended February 26, 2018, we received 2 unrelated comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety dangers with aerial maneuvers conducted by