

Extensible Mark-Up Language (XML) needed to make Electric Quarterly Report (EQR) filings with one of the new filing processes adopted in Order No. 770.<sup>1</sup> The Commission is also posting CSV file samples. Order No. 770 revised the process for filing EQRs. Pursuant to Order No. 770, one of the new processes for filing allows EQRs to be filed using an XML file. The XML schema that is needed to file EQRs in this manner is now posted on the Commission's Web site at <http://www.ferc.gov/docs-filing/eqr.asp>. While this schema remains subject to any necessary changes prior to the availability of the finalized schema, Commission staff anticipates that changes, if any, will be minor.

Any comments or questions concerning the XML schema may be directed to [eqr@ferc.gov](mailto:eqr@ferc.gov). Please include "XML Schema" in the subject line of any such email.

We encourage all EQR filers to subscribe to our *EQR RSS Feed* to stay up-to-date on all updates.

Dated: May 8, 2013.

**Kimberly D. Bose,**  
*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 880

[Docket No. FDA-2013-M-0042]

#### Medical Devices; General Hospital and Personal Use Monitoring Devices; Classification of the Ingestible Event Marker

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

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the ingestible event marker into class II (special controls). The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

**DATES:** This order is effective June 17, 2013. The classification was applicable beginning July 10, 2012.

**FOR FURTHER INFORMATION CONTACT:** James Cheng, Center for Devices and

Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1326, Silver Spring, MD 20993-0002, 301-796-6306.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or 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) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144, July 9, 2012, 126 Statute 1054), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of "low-

moderate risk" or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will 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 this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on May 7, 2012, classifying the Proteus Personal Monitor including ingestible event marker into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On May 14, 2012, Proteus Biomedical, Inc., submitted a petition requesting classification of the Proteus Personal Monitor including ingestible event marker under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition and the medical literature, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name ingestible event marker, and it is identified as a prescription device used to record time-stamped, patient-logged events. The ingestible component links wirelessly through intrabody communication to an external recorder which records the date and time of ingestion as well as the unique serial number of the ingestible device.

FDA has identified the following risks to health associated with this type of

<sup>1</sup> Revisions to Electric Quarterly Report Filing Process, Order No. 770, 77 FR 71288 (Nov. 30, 2012), FERC Stats. & Regs. [Regulation Preambles] ¶ 31,338 (cross-referenced at 141 FERC ¶ 61,120) (Nov. 15, 2012).

device and the measures required to mitigate these risks:

TABLE 1—INGESTIBLE EVENT MARKER RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction .....	Biocompatibility Testing. Labeling (dose limits).
Systemic toxicity .....	Toxicology Testing. Labeling (dose limits).
Electromagnetic incompatibility .....	Electromagnetic Compatibility Testing. Wireless Testing. Labeling.
Electrical safety issues .....	Electrical Safety Testing. Labeling.
Electrical/Mechanical failure .....	Nonclinical Performance Testing.
Failure to mark event .....	Nonclinical Performance Testing. Clinical Evaluation.
Failure to excrete .....	Animal Testing.
Usability .....	Human Factors Testing. Labeling.

FDA believes that the following special controls, in addition to the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness:

1. The device must be demonstrated to be biocompatible and non-toxic;
2. Nonclinical, animal, and clinical testing must provide a reasonable assurance of safety and effectiveness, including device performance, durability, compatibility, usability (human factors testing), event recording, and proper excretion of the device;
3. Appropriate analysis and nonclinical testing must validate electromagnetic compatibility performance, wireless performance, and electrical safety; and
4. Labeling must include a detailed summary of the nonclinical and clinical testing pertinent to use of the device and the maximum number of daily device ingestions.

Ingestible event markers are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device. (Proposed § 880.6305(a) (21 CFR 880.6305(a)); see section 520(e) of the FD&C Act (21 U.S.C. 360j(e)) and § 801.109 (21 CFR 801.109) (Prescription devices).) Prescription-use restrictions are a type of general controls authorized under section 520(e) and defined as a general control in section 513(a)(1)(A)(i) of the FD&C Act.

Therefore, on July 10, 2012, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying the classification of the device by adding § 880.6305.

Following the effective date of this final classification administrative order, any firm submitting a 510(k) premarket

notification for an ingestible event marker will need to comply with the special controls named in the final administrative order.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) 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 device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification prior to marketing the device, which contains information about the ingestible event marker they intend to market.

**II. Environmental Impact**

The Agency has 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.

**III. 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, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

**IV. Reference**

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. Petition: Request for Evaluation of Automatic Class III Designation Under Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act From Proteus Biomedical, Inc., dated May 9, 2012.

**List of Subjects in 21 CFR Part 880**

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act 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 21 CFR part 880 continues to read as follows:

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

- 2. Add § 880.6305 to subpart G to read as follows:

**§ 880.6305 Ingestible event marker.**

(a) *Identification.* An ingestible event marker is a prescription device used to record time-stamped, patient-logged events. The ingestible component links wirelessly through intrabody communication to an external recorder which records the date and time of ingestion as well as the unique serial number of the ingestible device.

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

(1) The device must be demonstrated to be biocompatible and non-toxic;

(2) Nonclinical, animal, and clinical testing must provide a reasonable assurance of safety and effectiveness, including device performance, durability, compatibility, usability (human factors testing), event recording, and proper excretion of the device;

(3) Appropriate analysis and nonclinical testing must validate electromagnetic compatibility performance, wireless performance, and electrical safety; and

(4) Labeling must include a detailed summary of the nonclinical and clinical testing pertinent to use of the device and the maximum number of daily device ingestions.

Dated: May 10, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF JUSTICE****Drug Enforcement Administration****21 CFR Part 1308**

[Docket No. DEA-373]

**Schedules of Controlled Substances: Temporary Placement of Three Synthetic Cannabinoids Into Schedule I**

**AGENCY:** Drug Enforcement Administration, Department of Justice.  
**ACTION:** Final order.

**SUMMARY:** The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this final order to temporarily schedule three synthetic cannabinoids under the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The substances are (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-

fluoro-UR-144, XLR11) and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48). This action is based on a finding by the Deputy Administrator that the placement of these synthetic cannabinoids and their salts, isomers and salts of isomers into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. As a result of this order, the full effect of the CSA and the Controlled Substances Import and Export Act (CSIEA) and their implementing regulations including criminal, civil and administrative penalties, sanctions and regulatory controls of Schedule I substances will be imposed on the manufacture, distribution, possession, importation, and exportation of these synthetic cannabinoids.

**DATES:** *Effective Date:* This Final Order is effective on May 16, 2013.

**FOR FURTHER INFORMATION CONTACT:** John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; telephone (202) 307-7165.

**SUPPLEMENTARY INFORMATION:****Background**

Section 201 of the CSA (21 U.S.C. 811) provides the Attorney General with the authority to temporarily place a substance into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid imminent hazard to the public safety. 21 U.S.C. 811(h). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling up to one year.

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA (21 U.S.C. 812) or if there is no exemption or approval in effect under section 505 of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 355) for the substance (21 U.S.C. 811(h)(1)). The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of DEA, who in turn has delegated her authority to the Deputy Administrator of DEA. 28 CFR 0.100, Appendix to Subpart R.

Section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the Deputy Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into

Schedule I of the CSA.<sup>1</sup> The Deputy Administrator has transmitted notice of his intent to place UR-144, XLR11 and AKB48 in Schedule I on a temporary basis to the Assistant Secretary by letter dated February 14, 2013. The Assistant Secretary responded to this notice by letter dated March 14, 2013 (received by DEA on March 21, 2013), and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for UR-144, XLR11 or AKB48. The Assistant Secretary also stated that HHS has no objection to the temporary placement of UR-144, XLR11 or AKB48 into Schedule I of the CSA. DEA has taken into consideration the Assistant Secretary's comments (21 U.S.C. 811(h)(4)). As UR-144, XLR11 and AKB48 are not currently listed in any schedule under the CSA, and as no exemptions or approvals are in effect for UR-144, XLR11 and AKB48 under Section 505 of the FD&C Act (21 U.S.C. 355), DEA believes that the conditions of 21 U.S.C. 811(h)(1) have been satisfied. On April 12, 2013, a Notice of Intent to temporarily schedule these three synthetic cannabinoids was published in the **Federal Register** (78 FR 21858).

To make a finding that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Deputy Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA (21 U.S.C. 811(h)(3)). These factors are as follows: the substance's history and current pattern of abuse; the scope, duration and significance of abuse, and what, if any, risk there is to the public health. 21 U.S.C. 811(c)(4)-(6). Consideration of these factors includes actual abuse, diversion from legitimate channels and clandestine importation, manufacture or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling (21 U.S.C. 811(h)) may only be placed in Schedule I. Substances in Schedule I are those that have a high potential for

<sup>1</sup> Because the Secretary of the Department of Health and Human Services (HHS) has delegated to the Assistant Secretary for Health of the Department of Health and Human Services the authority to make domestic drug scheduling recommendations, for purposes of this Final Order, all subsequent references to "Secretary" have been replaced with "Assistant Secretary." As set forth in a memorandum of understanding entered into by HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the Controlled Substance Act (CSA), with the concurrence of NIDA. 50 FR 9518.