FAA–2015–0932; Directorate Identifier 2014–NM–205–AD.

(a) Effective Date

This AD is effective December 28, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 747–8 series airplanes, certificated in any category, as identified in Boeing Special Attention Service Bulletin 747–25–3649, dated July 24, 2014.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by a report of improperly installed outboard stowage bin modules in the passenger compartment found during maintenance. Further investigation revealed that certain attachment bracket bushings were missing or had moved out of the holes. We are issuing this AD to prevent detachment of the quick-release pin, which could result in separation of the lateral support tie rod and subsequent detachment of the module and consequent injuries to passengers or flightcrew.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Installation

Within 36 months after the effective date of this AD: Install a spacer on the end of each quick-release pin that attaches the outboard stowage bin module to the lateral support tie rods of the main deck passenger compartment, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–25–3649, dated July 24, 2014.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the Seattle ACO, send it to the attention of the person identified in paragraph (i) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (h)(3)(i) and (h)(3)(ii) apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(i) Related Information

For more information about this AD, contact Stanley Chen, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6585; fax: 425–917–6590; email: *stanley.chen@faa.gov.*

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Special Attention Service Bulletin 747–25–3649, dated July 24, 2014.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on November 4, 2015.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–28897 Filed 11–19–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 150

[Docket No. FDA–1997–P–0007 (formerly Docket No. 1997P–0142)]

Artificially Sweetened Fruit Jelly and Artificially Sweetened Fruit Preserves and Jams; Revocation of Standards of Identity

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is revoking the standards of identity for artificially sweetened jelly, preserves, and jams. We are taking this action primarily in response to a citizen petition submitted by the International Jelly and Preserve Association (IJPA). We also are taking this action because these standards are obsolete and unnecessary in light of our regulations for foods named by use of a nutrient content claim and a standardized term. This action will promote honesty and fair dealing in the interest of consumers.

DATES: The final rule is effective on November 20, 2015.

FOR FURTHER INFORMATION CONTACT: Terri Wenger, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION:

I. Background

For more than 50 years, we have maintained standards of identity for fruit jelly (jelly) (§ 150.140 (21 CFR 150.140)) and fruit preserves and jams (preserves and jams) (§ 150.160). The standards establish the common or usual name for these products and provide that these products may contain nutritive sweeteners (*e.g.,* sugar). In 1959, we added new standards of identity for artificially sweetened fruit jelly (artificially sweetened jelly) (§ 150.141) and artificially sweetened fruit preserves and jams (artificially sweetened preserves and jams) (§ 150.161) (24 FR 8896; October 31, 1959) that permit the use of non-nutritive sweeteners (*e.g.,* saccharin). Notably, §§ 150.141 and 150.161 limit the types of non-nutritive sweeteners that can be used in products that are governed by those standards of identity. Under §§ 150.141 and 150.161, such products may only use saccharin,

sodium saccharin, calcium saccharin, or any combination thereof, and may not use newer forms of non-nutritive sweeteners that have been developed since the standard of identity regulations were issued.

The Nutrition Labeling and Education Act (NLEA) of 1990 amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to provide for a number of fundamental changes in food labeling, leading to a new regulatory framework for the naming of foods that do not fully comply with the relevant standards of identity. In response to NLEA, we established in part 101 (21 CFR part 101), among other things, definitions for specific nutrient content claims using terms such as ''free'', ''low'', ''light'' or ''lite'', and ''less'', and provided for their use in food labeling (58 FR 2302; January 6, 1993). We also prescribed, in § 130.10 (21 CFR 130.10), a general definition and standard of identity for foods named by a nutrient content claim defined in part 101, such as ''low calorie'' or ''sugar free'', in conjunction with a traditional standardized food term (58 FR 2431; January 6, 1993). A nutrient content claim applied to the standardized food ''grape jelly'', for example, could be ''low calorie grape jelly''. Section 130.10(d)(1) allows the addition of safe and suitable ingredients to a food named by use of a nutrient content claim and a standardized term when these ingredients are used to, among other things, add sweetness to ensure that the modified food is not inferior in performance characteristics to the standardized food even if such ingredients are not specifically provided for by the relevant food standard. Thus, under certain circumstances, § 130.10 permits manufacturers to use safe and suitable artificial sweeteners (*e.g.,* sucralose) that are not expressly listed in §§ 150.141 and 150.161 in the manufacture of jelly, fruit preserves, and jams (collectively, ''fruit spreads''). Therefore, fruit spread products named with a nutrient content claim (for example, ''low calorie grape jelly'') may contain newer artificial sweeteners to add sweetness to fruit spread products so that they are not inferior in their sweetness compared to their standardized counterparts (for example, ''grape jelly''). Section 130.10 does not require these products to declare the presence of such non-nutritive sweeteners within the name of these foods. We took this action to help consumers in maintaining healthy dietary practices by providing for a modified version of a traditional standardized food to achieve a nutrition goal (*e.g.,* reduction in sugar consumption or calories) and that has a descriptive name that is meaningful to consumers. Section 130.10 does not, however, permit the use of nutrient content claims as part of the name of a food for foods governed by standards of identity that established the phrase ''artificially sweetened'' as part of the standard of identity. Accordingly, jelly, preserves, and jams, that use saccharin, sodium saccharin, calcium saccharin, or any combination thereof as non-nutritive sweeteners must still include the term ''artificially sweetened'' in their names and are not permitted to bear a nutrient content claim as part of the name. However, similar products that use newer non-nutritive sweeteners are governed by § 130.10 and are not required to include the term ''artificially sweetened'' in their names.

In the **Federal Register** of December 4, 2012, we proposed to revoke the standards of identity for artificially sweetened jelly, preserves, and jam in §§ 150.141 and 150.161 (77 FR 71746). The proposed rule was in response to a citizen petition submitted by the IJPA requesting such a revocation. In issuing the notice of proposed rulemaking, we stated that we found merit in the argument made in IJPA's petition that revoking §§ 150.141 and 150.161 would allow manufacturers to more accurately and consistently describe the attributes of the fruit spreads that currently conform to those regulations. We therefore tentatively concluded that revoking the standards of identity for artificially sweetened jelly, preserves, and jams would promote honesty and fair dealing in the interest of consumers and was thus appropriate under section 401 of the FD&C Act (21 U.S.C. 341). We tentatively reached this conclusion because we found that nutrient content claims such as ''low calorie'' or ''reduced sugar'' better characterize the nutritional profile of the affected fruit spreads than does the term ''artificially sweetened''. Further, we stated that revoking §§ 150.141 and 150.161 would provide manufacturers with the flexibility to use the three non-nutritive sweeteners listed in those standards while also naming their products using FDA-defined nutrient content claims, in accordance with § 130.10. We also noted that other safe and suitable artificial sweeteners that might be developed in the future could be used in these products under § 130.10 without the need to further revise relevant standards of identity, and that the proposed rule was consistent with FDA's proposed general principles for modernizing food standards (70 FR 29214; May 20, 2005).

II. Comments to the Proposed Rule and FDA's Responses

We received 21 comments to the proposed rule. The comments were from trade associations, food companies, and individuals. Two comments were identical, and another comment appeared to have been misdirected because it pertained to blogs. Most of the comments made general remarks supporting or opposing the rule and did not focus on a particular component of the rule.

Six comments supported the proposed rule. One comment stated that the proposed rule would provide flexibility to industry to use artificial sweeteners and to not use the term ''artificially sweetened'' in the name of their products. The comment also stated that the proposed rule would provide consistency and uniformity in the labeling of fruit spreads. Several comments stated that §§ 150.141 and 150.161 limit the type of non-nutritive sweeteners, and that enactment of the NLEA and FDA's regulation in § 130.10 allow flexibility. One of the comments also stated that the use of nutrient content claims such as ''reduced sugar'' in accordance with § 130.10 provides a better way to communicate with consumers to meet their nutritional goals.

In contrast, other comments opposed the proposed rule. Several comments said that the rule would remove transparency that allows consumers to make knowledgeable decisions. Another expressed concern that the non-nutritive sweeteners would not be labeled and that consumers would be cheated. Still others stated that removing the term ''artificially sweetened'' is deceitful, would allow harmful chemicals to be hidden in food, and would not protect consumers.

The final rule will not result in the declaration of non-nutritive sweeteners being removed from labels and will not result in substances being hidden in food. In accordance with § 101.4(a) (21 CFR 101.4(a)), ingredients (including non-nutritive sweeteners) must be declared by common or usual name on either the principal display panel or the information panel of the label. Thus, for example, the ingredient panel must list any non-nutritive sweeteners, including, for example, the three saccharin products currently subject to §§ 150.141 and 150.161 and any of the newer non-nutritive sweeteners such as sucralose. What the final rule will do is require any food products currently subject to §§ 150.141 and 150.161 to instead be subject to § 130.10. Although § 130.10 does not require products to declare the

presence of non-nutritive sweeteners within the name of these foods (*e.g.,* § 130.10 does not require a jam made with a non-nutritive sweetener to be named ''artificially sweetened jam''), it does require foods subject to that provision to be named by use of a nutrient content claim defined in part 101 (*e.g.,* ''reduced calorie'' or ''no sugar added''). Nutrient content claims such as ''low calorie'' or ''no sugar added'' better characterize the nutritional profile of the fruit spreads currently subject to §§ 150.141 and 150.161 than does the term ''artificially sweetened.'' The final rule will also allow better comparison to other jams, jellies, and preserves currently modified under the provisions of § 130.10. For example, under current requirements, a jelly that is sweetened with saccharin must be called ''artificially sweetened jelly'' (in accordance with § 150.141), whereas a similar jelly sweetened with sucralose may be named as ''reduced sugar jelly'' (in accordance with § 130.10 and provided it meets the requirements for the nutrient content claim ''reduced sugar'' in § 101.60(c)(5) to distinguish it from the standardized food (jelly in § 150.140). Revoking the standards will provide consistency and uniformity among such products because all fruit spreads sweetened with non-nutritive sweeteners will be subject to the same requirements. For these reasons, the final rule will promote honesty and fair dealing in the interest of consumers consistent with section 401 of the FD&C Act.

As for the comment that artificial sweeteners are ''toxic'' or ''dangerous,'' that comment does not address the merits of revoking §§ 150.141 and 150.161.

III. Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we have concluded, as set forth in this document, that this rule will not generate significant compliance costs, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. We do not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

A. Need for This Regulation

We are revoking the standards of identity for artificially sweetened jelly, preserves, and jams because these standards are obsolete and unnecessary. The current standards of identity for artificially sweetened jelly (§ 150.141) and artificially sweetened preserves and jams (§ 150.161) provide that they may be manufactured only with specific, non-nutritive artificial sweeteners: Saccharin, sodium saccharin, calcium saccharin, or any combination thereof. These standards of identity, therefore, do not permit the use of newer, safe, and suitable artificial sweeteners, such as sucralose.

The development of newer artificial sweeteners and the enactment of the NLEA have made the current standards of identity for artificially sweetened jelly, preserves, and jams obsolete. The NLEA and § 130.10 permit the modification of a traditional standardized food to achieve a nutrition goal, such as a reduction in calories. Section 130.10(d)(1) allows the addition of safe and suitable ingredients to a food named by use of a nutrient content claim and a standardized term when these ingredients are used to, among other things, add sweetness to ensure that the modified food is not inferior in performance characteristic to the standardized food, even if such ingredients are not specifically provided for by the relevant food standard.

Standardized jelly and standardized preserves and jams products modified under § 130.10 must use nutrient content claims to communicate the modified standardized product's nutritional profile to consumers. Under § 130.10, nonspecific, safe, and suitable artificial sweeteners other than the three named in §§ 150.141 and 150.161 can be used to make reduced calorie or reduced sugar products labeled with a nutrient content claim that is established in FDA regulations. Revoking the standards of identity means that any product subject to §§ 150.141 and 150.161 will instead be subject to § 130.10. This will allow consumers to better compare any fruit spreads currently covered by §§ 150.141 and 150.161 with other spreads that are named and modified under the provisions of § 130.10. Revoking the standards also gives manufacturers the flexibility to use the three non-nutritive sweeteners listed in §§ 150.141 and 150.161, while naming their products under § 130.10 using a defined nutrient content claim.

B. Regulatory Options

In assessing our regulatory options, we considered the option of taking no action and the option of implementing this final rule. We conclude that the rule is not an economically significant regulatory action. We are not quantitatively estimating the benefits and costs of the regulatory alternatives to the rule. In the following paragraphs, we qualitatively compare the costs and benefits of the regulatory options to the costs and benefits of the rule.

1. The Option of Taking No Action

By convention, we treat the option of taking no new regulatory action as the baseline for determining the costs and benefits of the other options. Therefore, we associate neither costs nor benefits with this option. The consequences of taking no action are reflected in the costs and benefits associated with taking the action set forth in this rule.

2. The Option of Implementing the Final Rule

By revoking §§ 150.141 and 150.161, products that are currently subject to the requirements of these standards of identity will no longer be required to use the phrase ''artificially sweetened'' as part of their product name. Furthermore, revoking §§ 150.141 and 150.161 means that these same products will be permitted to bear nutrient content claims along with a standardized term (*e.g.,* ''reduced calorie jelly'' or ''no sugar added jam''), in accordance with § 130.10.

The costs of this rule result from the need to relabel any existing jelly, preserves, and jams that conform with §§ 150.141 and 150.161. Any products currently manufactured in accordance with the standards in §§ 150.141 and

150.161 will have to be relabeled in order to comply with § 130.10. Our review of supermarket scanner data for the years 2001 through 2010, however, revealed that no such products are currently being sold. Sales for products manufactured and labeled in accordance with §§ 150.141 and 150.161 were last reported in 2002. A memorandum summarizing the results of this scanner data can be found in Reference 1. The data support our conclusion that most manufacturers most likely have discontinued production of jelly, preserves, and jams that must be labeled as ''artificially sweetened,'' presumably because of a perception that the phrase ''artificially sweetened'' is unattractive to consumers. The data also support our conclusion that it is unlikely that the rule will generate significant compliance costs due to the need to relabel products. In fact, removal of the artificially sweetened standards of identity will allow manufacturers to re-introduce products covered under §§ 150.141 and 150.161 to be sold as products covered by § 130.10. That is, such products would be named by use of a nutrient content claim in conjunction with a standardized term (*e.g.,* ''reduced calorie jelly'' or ''no sugar added jam''), in accordance with § 130.10. Therefore, we conclude that any relabeling compliance costs will be negligible.

We do not classify as anticipated costs of this rule any expenses that firms might voluntarily incur if they choose to change their product formulas or manufacturing practices. Any such costs are not costs that would be required by the rule. Instead, these costs would result from voluntary business decisions made by manufacturers.

We conclude that the principal benefits that will result from the rule derive from increased information and flexibility. Revoking the artificially sweetened standards of identity will provide producers of jelly, preserves, and jams with the flexibility to use saccharin, sodium saccharin, calcium saccharin, or any combination thereof, in their formulations without having to include the term ''artificially sweetened'' in their product names. Manufacturers could instead name their products in accordance with approved nutrient content claims, as provided for under § 130.10, thus providing consumers with additional information about the nutritional profile of affected products. Additionally, revoking §§ 150.141 and 150.161 will help consumers compare products covered by the standards with other similar jelly, preserves, and jams manufactured in accordance with § 130.10.

Accordingly, while we do not quantify the costs and benefits of the rule, we conclude that potential benefits will outweigh any potential costs associated with the rule.

C. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because compliance costs, if any, generated by this rule are expected to be negligible, we conclude that this rule will not have a significant economic impact on a substantial number of small entities. The following analysis, in conjunction with the discussion in this document, constitutes our final regulatory flexibility analysis as required by the Regulatory Flexibility Act.

The rule revokes the standards of identity for artificially sweetened jelly, preserves, and jams. The revocation of these artificially sweetened standards of identity gives small fruit spread firms the flexibility to use the three non-nutritive sweeteners listed in §§ 150.141 and 150.161 and to name their products with FDA-defined nutrient content claims in accordance with § 130.10, as is currently done for fruit spread products manufactured with other non-nutritive sweeteners.

We do not classify as costs of this rule any expenses that some small firms might voluntarily incur because they choose to change their product formulas or manufacturing practices. As discussed in this document, any such costs would not be costs required by this rule.

IV. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to ''construe a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority 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 any requirement for a food which is the subject of a standard of identity established under section 401 (of the FD&C Act) that is not identical to such standard of identity or that is not identical to the requirement of section 403(g) of the FD&C Act (21 U.S.C. 343(g)). 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 NLEA, Pub. L. 101–535, 104 Stat. 2353, 2364 (1990)).

This final rule will impose requirements that fall within the scope of section 403A(a) of the FD&C Act.

V. Environmental Impact

We have determined under 21 CFR 25.32(a) 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.

VI. Paperwork Reduction Act

This final rule contains no collection of information. Therefore, clearance by Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Reference

The following reference is on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *http://www.regulations.gov.* FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. A.C. Nielsen Scantrack data, (2001–2010). The Nielsen Company, 770 Broadway, New York, NY 10003–9595 (*http://www.acnielsen.com/*).

List of Subjects in 21 CFR Part 150

Food grades and standards, Fruits.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 150 is amended as follows:

PART 150—FRUIT BUTTERS, JELLIES, PRESERVES, AND RELATED PRODUCTS

■ 1. The authority citation for 21 CFR part 150 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

§ 150.141 [Removed]

■ 2. Remove § 150.141.

§ 150.161 [Removed]

■ 3. Remove § 150.161.

Dated: November 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29631 Filed 11–19–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA–2014–N–1243]

Dental Devices; Reclassification of Electrical Salivary Stimulator System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify the salivary stimulator system, a postamendments Class III device, into class II (special controls) and to rename the device the ''electrical salivary stimulator system.'' 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 December 21, 2015.

FOR FURTHER INFORMATION CONTACT: Michael Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993, 301–796–6283.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended, 21 U.S.C. 301 *et seq.,* 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) of the FD&C Act. Section 513(f)(3) 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 section 513(f)(3) of the FD&C Act must be ''valid scientific evidence'', as defined in section 513(a)(3) 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 Mfrs. 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 premarket approval application (PMA) (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).

On September 18, 2014, FDA published an order in the **Federal Register** to reclassify the device (79 FR 56027) (the ''proposed order''). The period for public comment on the proposed order closed on December 17, 2014. FDA received and has considered 20 comments on the proposed order, as discussed in section II.

II. Public Comments in Response to the Proposed Order

Of the 20 public comments that FDA received in response to the proposed order, 17 comments supported the proposed reclassification and 3 comments were opposed. All of the commenters were individuals, 12 of whom identified themselves as medical practitioners. Eight of these 12 practitioners claimed prior research experience with the device. Three commenters claimed experience with the device as patients in clinical trials.

All of the practitioners' and patients' comments were supportive of the reclassification proposal. All of the practitioners with prior experience administering the device noted favorable results for some of their patients and no adverse events. The other four practitioners who commented either had recommended, or if available would recommend, the device as a non-pharmaceutical option for treating dry mouth conditions.

Five commenters did not claim any prior professional or patient experience with the device. Of these comments, two favored finalization of the proposed reclassification based on the evidence presented in the proposed order.

Three comments opposed the proposed reclassification. None of these commenters claimed prior professional or patient experience with the device. One commenter believed that the proposed order adequately addressed safety concerns but failed to provide convincing evidence of the effectiveness of the device.

FDA disagrees with the comment. The special control requiring documented clinical experience will allow the Agency to require information on each device's effectiveness in actual clinical use.

Two commenters believed that the devices should undergo further clinical trials to evaluate device and human factors risks, and that electrically powered salivary stimulators are inherently hazardous and subject to misuse and, without conclusive test results, should continue to be classified as Class III devices and be subject to premarket approval.

The Agency disagrees that electrical salivary stimulator systems should