**Q–5 SPAMY, CA to HAROB, WA [Amended]**

| | | |
|---|---|---|
| SPAMY, CA | WP | (Lat. 39°11′57.00″ N, long. 122°37′58.00″ W) |
| HOMEG, CA | WP | (Lat. 41°20′09.00″ N, long. 122°51′05.00″ W) |
| HARPR, OR | WP | (Lat. 42°28′50.00″ N, long. 122°53′01.54″ W) |
| HISKU, OR | WP | (Lat. 44°30′00.00″ N, long. 122°56′39.00″ W) |
| HAROB, WA | WP | (Lat. 47°14′36.00″ N, long. 123°02′27.00″ W) |

Issued in Washington, DC, on March 13, 2018.

**Rodger A. Dean Jr.,**

*Manager, Airspace Policy Group.*

[FR Doc. 2018–05584 Filed 3–20–18; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 4

**[Docket No. FDA–2008–N–0424]**

## Postmarketing Safety Reporting for Combination Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

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

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry and FDA staff entitled ''Postmarketing Safety Reporting for Combination Products.'' This draft guidance addresses certain means by which applicants may comply with the final rule on postmarketing safety reporting (PMSR) requirements for combination products that FDA issued on December 20, 2016. Combination products are products composed of two or more different types of medical products (drug, device, and/or biological product). Although the PMSR regulations for drugs, devices, and biological products share many similarities, each set of regulations establishes distinct postmarketing reporting requirements, standards, and timeframes. The final rule provides clarity on the PMSR requirements for combination products to ensure consistent and complete reporting while avoiding duplication. This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by June 19, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit either electronic or written comments on any 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–2008–N–0424 for ''Postmarket Safety Reporting for Combination Products.'' 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*.

*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 draft guidance to the Office of Combination Products, Food and Drug Administration, Bldg. 32, Rm. 5129, 10903 New Hampshire Ave., Silver Spring, MD 20993. Send two self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section

for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Melissa Burns, Office of Combination Products, Food and Drug Administration, 301–796–5616, *melissa.burns@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Postmarket Safety Reporting for Combination Products.'' This guidance addresses how to comply with the final rule on postmarketing safety reporting (PMSR) requirements for combination products that FDA issued on December 20, 2016 (81 FR 92603, hereafter referred to as the ''combination product PMSR final rule''). Combination products are products composed of two or more different types of medical products (drug, device, and/or biological product). Although the PMSR regulations for drugs, devices, and biological products share many similarities, each set of regulations establishes distinct reporting requirements, standards, and timeframes. The final rule provides clarity on the PMSR requirements for combination products to ensure consistent and complete reporting while avoiding duplication.

Elsewhere in this issue of the **Federal Register**, FDA is also publishing a compliance policy guidance for the combination product PMSR final rule.

The combination product PMSR final rule applies to combination products that are subject to premarket review by FDA. The entities subject to the final rule are ''Combination Product Applicants'' and ''Constituent Part Applicants.'' A Combination Product Applicant holds the only application for a combination product or all the applications for the separately marketed constituent parts of a combination product. A Constituent Part Applicant holds an application for a constituent part of a combination product the constituent parts of which are marketed under separate applications held by different applicants. Major provisions of the final rule are discussed in the guidance including:

- *Application Type-Based PMSR.* These requirements apply to both Combination Product Applicants and Constituent Part Applicants and are based on the application type under which the combination product or constituent part received marketing authorization.
- *Constituent Part-Based PMSR.* These requirements apply only to Combination Product Applicants and are based on the types of constituent parts included in the combination product. The rule provides mechanisms for Combination Product Applicants to submit a single report to satisfy multiple reporting requirements if all of the information to be reported can be submitted in the same manner and the report satisfies all applicable reporting requirements, including all submission timelines.
- *Information Sharing.* These requirements apply only to Constituent Part Applicants, mandating that these applicants share certain adverse event information with one another relating to their combination product.
- *Submission Process for Combination Product PMSR Information.* These requirements specify how Combination Product and Constituent Part Applicants must submit PMSR information to the Agency.
- *Records Retention.* These requirements specify what records Combination Product and Constituent Part Applicants must maintain and how long to maintain them.

## II. Other Issues for Consideration

The combination product PMSR final rule allows FDA to receive complete, timely postmarketing safety information regarding combination products, which is necessary to assure the continued safety and effectiveness of such products, while minimizing unnecessary duplication and burdens on Combination Product Applicants and Constituent Part Applicants. In developing this guidance document to accompany the final rule, FDA has clarified ways in which Combination Product Applicants can streamline PMSR (see section V.A.3 of the guidance). The guidance clarifies under what circumstances the criteria for being able to submit a single report to FDA are met, *i.e.,* that: (1) The reports can be submitted in the same manner and (2) the combined report satisfies all applicable reporting requirements, including submission timelines (see section IV.C of the guidance). FDA encourages comments on guidance content and mechanisms to improve reporting efficiency while still ensuring complete and timely reporting or topics where additional detailed discussion may be helpful in the guidance. In particular, FDA requests feedback on the following issues for consideration to assist the Agency in determining whether additional streamlining of reports may be appropriate:

1. There may be events that would be reportable for a Combination Product Applicant as a malfunction and/or a Field Alert Report (FAR) and/or a Biological Product Deviation Report (BPDR), *e.g.,* a drug-device combination product that failed to meet specifications may trigger both a malfunction report and FAR. FDA requests feedback on circumstances under which such reporting may be redundant or otherwise unnecessary and, if so, alternative reporting approaches that will assure timely and complete reporting of information to FDA. FDA encourages the use of example scenarios to illustrate circumstances under which submitting one or a subset of such reports may be sufficient to ensure timely and complete reporting.

2. Although outside the scope of the combination product PMSR final rule, in response to comments to the combination product PMSR proposed rule, FDA has addressed certain reporting considerations for entities involved with the manufacture and distribution of combination products but that are not ''applicants'' subject to this rule (see Appendix 3 of the guidance). FDA requests feedback on what, if any, additional guidance would be helpful to such entities.

3. FDA is considering updating the Vaccine Adverse Event Reporting System (VAERS) with data elements similar to those described in section V.B.2 and Appendix 4 of the guidance for the FDA Adverse Events Reporting System (FAERS) and the Electronic Medical Device Reporting (eMDR) system. FDA is also evaluating what additional data elements to include in VAERS with respect to combination products and welcomes comments from combination product vaccine reporters on this topic.

4. FDA also received comments to the combination product PMSR proposed rule related to the safety reporting requirements for investigational combination products. Although investigational combination products are outside the scope of the combination product PMSR final rule and this guidance, we will consider comments from sponsors on the challenges and the need for additional transparency related to safety reporting for investigational combination products. FDA will consider these comments in determining the need for additional policy and guidance on this topic.

## III. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA

on ''Postmarket Safety Reporting for Combination Products.'' 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.

### IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314.80(c) and (e), as well as for 21 CFR 314.81(b) are approved under OMB control numbers 0910–0001, 0910–0230, and 0910–0291. The information collection provisions for 21 CFR 600.80 and 600.81 are approved under OMB control number 0910–0308. Those for 21 CFR 606.170 are approved under OMB control number 0910–0116. Those for 21 CFR 606.171 are approved under OMB control number 0910–0458. The information collection provisions for 21 CFR 803.50, 803.53, and 803.56 are approved under OMB control numbers 0910–0291 and 0910–0437. The information collection provisions for 21 CFR 806.10 and 806.20 are approved under OMB control number 0910–0359. The information collection provisions for 21 CFR 4.102, 4.103, and 4.105 are approved under OMB control number 0910–0834.

### V. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm109110.htm* or *https://www.regulations.gov*.

Dated: March 15, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–05687 Filed 3–20–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 1100, 1140, and 1143

**[Docket No. FDA–2017–N–6565]**

**RIN 0910–AH60**

## Regulation of Flavors in Tobacco Products

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

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to obtain information related to the role that flavors play in tobacco products. Specifically, this ANPRM is seeking comments, data, research results, or other information about, among other things, how flavors attract youth to initiate tobacco product use and about whether and how certain flavors may help adult cigarette smokers reduce cigarette use and switch to potentially less harmful products. FDA is seeking this information to inform regulatory actions FDA might take with respect to tobacco products with flavors, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). Potential regulatory actions include, but are not limited to, tobacco product standards and restrictions on sale and distribution of tobacco products with flavors.

**DATES:** Submit either electronic or written comments by June 19, 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 June 19, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of June 19, 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–6565 for ''Regulation of Flavors in Tobacco Products.'' 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