Dated: July 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–19622 Filed 8–3–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0518]

Notices of Filing of Petitions for Food Additives and Color Additives; Relocation in the Federal Register

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is notifying the public that notices of filing of petitions for food additives and color additives that are published in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) will now be published in the ''Proposed Rules'' section of the **Federal Register**. Notices of filing have historically been published in the ''Notices'' section of the **Federal Register**. The Office of the Federal Register (OFR) recently informed FDA that, under OFR rules, these documents actually fall into the ''Proposed Rules'' category and requested that FDA reclassify these notices of filing documents as proposed rules. This change is effective immediately.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Regulations Editorial Section, Office of Policy, Planning and Budget, Food and Drug Administration,10903 New Hampshire Ave., Bldg. 32, Rm. 3208, Silver Spring, MD 20993–0002, 301–796–9148, *joyce.strong@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 409 of the FD&C Act (21 U.S.C. 348) establishes the food additive petition approval process for food additives for use in human and animal food. Section 409(b)(5) requires that the Secretary of Health and Human Services publish notice in general terms of the receipt of a petition within 30 days of its filing. Similarly, section 721 of the FD&C Act (21 U.S.C. 379e) establishes a petition approval process for color additives used in food, drugs, cosmetics, and devices, and requires that the Secretary publish notice in general terms of the receipt of a color additive petition within 30 days of its filing. These responsibilities of the Secretary have been delegated to the Commissioner of Food and Drugs and redelegated to certain other FDA officials. These notices of filing are published in the **Federal Register**.

Under the **Federal Register** Act (44 U.S.C. chapter 15), the Administrative Committee of the **Federal Register** issues regulations regarding publishing documents in the **Federal Register** (1 CFR chapter I). Based on these governing regulations, the OFR classifies Agency documents published in the **Federal Register** in one of three categories: rules and regulations, proposed rules, and notices. The regulation establishing document types is 1 CFR 5.9. FDA's section 409 and section 721 notices of filing have historically been published in the ''Notices'' section of the **Federal Register**. OFR recently informed FDA that, in their view, these documents actually fall into the ''Proposed Rules'' category and requested that FDA classify future such notices of filing documents as proposed rules (Ref. 1).

Accordingly, FDA documents providing notice under section 409(b)(5) or section 721(d)(1) of the FD&C Act will appear in the proposed rule section of the **Federal Register**. This change is effective immediately.

II. 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.

1. Memo from Amy P. Bunk, Office of the Federal Register, to Joyce Strong, Food and Drug Administration, May 9, 2011.

Dated: July 29, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–19765 Filed 8–3–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–M–0323, FDA–2011–M–0256, FDA–2011–M–0257, FDA–2011–M–0241, FDA–2011–M–0284, FDA–2011–M–0295, FDA–2011–M–0300, FDA–2011–M–0296, FDA–2011–M–0342, FDA–2011–M–0338, FDA–2011–M–0343, FDA–2011–M–0348, FDA–2011–M–0349, FDA–2011–M–0430, FDA–2011–M–0431, FDA–2011–M–0445, FDA–2011–M–0470, FDA–2011–M–0472, FDA–2011–M–0502, and FDA–2011–M–0503]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993, 301–796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the Agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an