Dated: July 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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

BILLING CODE 4160–01–C

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]

BILLING CODE 4160–01–P

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

order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from April 1, 2011, through June 30, 2011. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM APRIL 1, 2011, THROUGH JUNE 30, 2011

PMA No./Docket No.	Applicant	Trade name	Approval date
P050050 FDA–2011–M–0323	Small Bone Innovations, Inc	Scandinavian total ankle replacement system	May 27, 2009.
P060004(S1) FDA–2011–M–0256	Carl Zeiss Meditec, Inc	Meditec MEL 80 excimer laser system	March 28, 2011.
P100040 FDA–2011–M–0257	Medtronic Vascular	Valiant thoracic stent graft system	April 1, 2011.
H100002 FDA–2011–M–0241	NeuroVasx, Inc	cPAX aneurysm treatment system	April 1, 2011.
P100018 FDA–2011–M–0284	Chestnut Medical Technologies, Inc.	Pipeline embolization device	April 6, 2011.
P100034 FDA–2011–M–0295	NovoCure, Ltd	NovoCure Ltd.'s NovoTTF–100A treatment kit	April 8, 2011.
P100020 FDA–2011–M–0300	Roche Molecular Systems, Inc	cobas HPV test	April 19, 2011.
P100029 FDA–2011–M–0296	St. Jude Medical, Inc	Trifecta heart valve	April 20, 2011.
P100023 FDA–2011–M–0342	Boston Scientific Corp	ION paclitaxel-eluting coronary stent system (mono-rail and over-the-wire systems).	April 22, 2011.
P930014 (S45) FDA–2011–M–0338.	Alcon Research, Ltd	AcrySof toric IOL and AcrySof IQ toric IOL	May 3, 2011.
P040012 (S34) FDA–2011–M–0343.	Abbott Vascular, Inc	RX Acculink carotid stent system	May 6, 2011.
P090028 FDA–2011–M–0348	Ortho-Clinical Diagnostics, Inc	Vitros immunodiagnostic products HBeAg reagent pack/products HBeAg calibrator/products HBe controls.	May 11, 2011.
P100017 FDA–2011–M–0349	Abbott Molecular, Inc	Abbott RealTi*m*e HCV, Abbott RealTi*m*e HCV amplification reagent kit, Abbott RealTi*m*e HCV control kit, Abbott RealTi*m*e HCV calibrator kit, and optional UNG Uracil-N-glycosylase.	May 17, 2011.
P100013 FDA–2011–M–0430	Cordis Corp	Cordis ExoSeal vascular closure device	May 19, 2011.
P070015 (S54) FDA–2011–M–0431.	Abbott Vascular	Xience nano everolimus-eluting coronary stent system and Promus everolimus-eluting coronary stent system.	May 24, 2011.
P100014 FDA–2011–M–0445	Oceana Therapeutics, Inc	Solesta injectable gel	May 27, 2011.
P090002 FDA–2011–M–0470	Depuy Orthopaedics, Inc	Pinnacle complete acetabular hip system	June 13, 2011.
P100027 FDA–2011–M–0472	Ventana Medical Systems, Inc	INFORM HER2 dual ISH DNA probe cocktail	June 14, 2011.
P100031 FDA–2011–M–0502	Roche Diagnostics Corp	Elecsys anti-HBc immunoassay and Elecsys PreciControl anti-HBc for use on the modular Analytics E170 immunoassay analyzer.	June 22, 2011.
P100032 FDA–2011–M–0503	Roche Diagnostics Corp	Elecsys anti-HBc immunoassay and Elecsys PreciControl anti-HBc for use on the Elecsys 2010 immunoassay analyzer.	June 27, 2011.

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: July 29, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–19734 Filed 8–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0332]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: Under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), the Food and Drug Administration (FDA) is required to report annually in the **Federal Register** on the status of postmarketing requirements and commitments required of, or agreed upon by, holders of approved drug and biological products. This notice is the Agency's report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct.

FOR FURTHER INFORMATION CONTACT: Beth Duvall-Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6466, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for