REPORT TO CONGRESS

Premarket Approval of Pediatric Uses of Devices – FY 2012

Submitted Pursuant to Section 515A of the Federal Food, Drug, and Cosmetic Act

U.S. Department of Health and Human Services

Food and Drug Administration

Executive Summary

Section 515A(a)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires the Food and Drug Administration (FDA) to submit an annual report to Congress that provides information concerning premarket approvals of devices labeled for pediatric use or for which there is a pediatric subpopulation that suffers from the disease that the device is intended to treat, diagnose, or cure. This is FDA's most recent report pursuant to this requirement. The report uses information from FDA's Center for Devices and Radiological Health and reflects approvals made during fiscal year (FY) 2012. In addition, this report provides background information about FDA's activities to facilitate the development of safe and effective pediatric devices. This report highlights the following information:

In FY 2012:

- FDA approved 49 original and panel track supplement premarket approval applications (PMAs)[i] and three humanitarian device exemption (HDE)[ii] applications.
- Among the 49 approvals, 19 PMA devices and one HDE device were approved for the treatment, diagnosis, or cure of a disease or condition which occurs within a pediatric subpopulation.
- FDA approved 10 PMA devices (20 percent of approved PMAs) and one HDE device labeled for use in a pediatric population or subpopulation.
- One approved device application was exempt from user fees because the device is intended solely for pediatric use.
- Information about each FY 2012 pediatric device approval, including its review time and the pediatric population for which it is labeled, appears in this report at Appendix A.

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I. Introduction

The Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85) amended section 515A of the FD&C Act, "Pediatric Uses of Devices" (21 U.S.C. 360e-1). Section 515A(a) of the FD&C Act requires persons who submit certain medical device applications to include, if readily available, a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients.

Section 515A(a)(3) of the FD&C Act requires FDA to submit an annual report to Congress that provides information concerning premarket approvals of devices labeled for pediatric use or for which there is a pediatric subpopulation that suffers from the disease that the device is intended to treat, diagnose, or cure.

Specifically, section 515A(a)(3) of the FD&C Act states that:

> *Not later than 18 months after the date of the enactment of this section and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes:*
>
> *(A) the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;*
>
> *(B) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;*
>
> *(C) the number of pediatric devices approved in the year preceding the year in which the report is submitted that were exempted from a fee pursuant to section 738(a)(2)(B)(v); and*
>
> *(D) the review time for each device described in subparagraphs (A), (B), and (C).*

This is FDA's third report pursuant to section 515A(a)(3) of the FD&C Act since FDAAA's enactment. The report provides the data and information required under section 515A(a)(3) of the FD&C Act for approvals made during FY 2012, as well as background information regarding section 515A of the FD&C Act and FDA's implementation of that provision.

II. Background

Section 515A of the FD&C Act and other provisions in FDAAA are intended to encourage the development of devices for use in pediatric patients. The House Report for FDAAA described the need for the legislation as follows:

> *Pediatric medical devices are used to treat or diagnose diseases and conditions in patients from birth through age 21 years. Some products are designed specifically for children, while others are borrowed from adult applications or produced for more general use.*
>
> *Children have specific medical needs that must be considered when medical and surgical devices are prescribed. Devices that have not been studied for use in children may not accommodate the unique needs of children, such as allowing for expandable growth and accommodating their active lifestyles and differing metabolism.*[1]

For purposes of this report, pediatric use devices are those which are labeled for use in pediatric patients or intended to treat, diagnose, or cure diseases from which pediatric patients suffer. In addition, for purposes of this report, the pediatric population is defined as those younger than 22 years of age (i.e., inclusive of the patient's 21st year of life). Pediatric subpopulations are defined in section 520(m)(6)(E)(ii) (and adopted by reference in section 515A(c) of the FD&C Act) to be: Neonates, Infants, Children, and Adolescents. Age ranges for these pediatric subpopulations are:

- Neonates (birth to 1 month of age);[2]
- Infants (older than 1 month to 2 years of age);
- Children (older than 2 years to 12 years of age); and
- Adolescents (older than 12 years through 21 years of age).

III. Summary of Information Required Under Section 515A(a)(3) of FD&C Act

In summary, in FY 2012:

- FDA approved 49 original and panel track supplement PMAs and three HDE applications.

- Among the 49 approvals, 19 PMA devices and one HDE device were approved for the treatment, diagnosis, or cure of a disease or condition which occurs within a pediatric subpopulation.

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[1] House Committee on Energy and Commerce, "Food and Drug Administration Amendments Act of 2007," H. Rept. 100-225, 110th Congress, 1st Session, on page 8.

[2] See *Pediatrics* 2011; 128:177-181; American Academy of Pediatrics; American College of Obstetrics and Gynecology: Appendix D: standard terminology for reporting reproductive health statistics. In: *Guidelines for Perinatal Care.* 6th ed. Elk Grove Village, Il: American Academy of Pediatrics; 2007: 389-404.

- FDA approved 10 PMA devices (20 percent of approved PMAs) and one HDE device labeled for use in a pediatric population or subpopulation.

- FDA approved one of these 10 PMAs for a device that was exempt from user fees because the device is intended solely for pediatric use.

IV. Conclusion

Information about each FY 2012 pediatric device approval, including the review times and the pediatric population for which it is labeled, appears in this report at Appendix A. The information contained in this 2012 report provides information and accounting with respect to the approval of devices that are labeled for use in pediatric patients or intended to treat, diagnose, or cure diseases from which pediatric patients suffer for FY 2012, as required by section 515A of the FD&C Act.

Appendix A
FY 2012 Device Approvals for Pediatric Patients with Review Times

FY 2012	
PMA Device Information	
TAXUS Express2 Paclitaxel-Eluting Coronary Stent System (Monorail and Over-the-Wire)	
Manufacturer	Boston Scientific Corporation
Number	P030025/S086
Filing Date	3/8/2010
Approval Date	2/22/2012
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	409
Total Review Days	716
TAXUS Liberté Paclitaxel-Eluting Coronary Stent System (Monorail and Over-the-Wire)	
Manufacturer	Boston Scientific Corporation
Number	P060008/S046
Filing Date	3/8/2010
Approval Date	2/22/2012
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	409
Total Review Days	716
Prometra Programmable Infusion Pump System	
Manufacturer	Flowonix Medical, Inc.
Number	P080012
Filing Date	4/11/2008
Approval Date	2/7/2012
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	877
Total Review Days	1397

PMA Device Information	
Belotero Balance transparent hyaluronic acid gel	
Manufacturer	Merz Aesthetics, Inc.
Number	P090016
Filing Date	7/23/2009
Approval Date	11/14/2011
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	335
Total Review Days	884
ION Paclitaxel-Eluting Coronary Stent System (Monorail and Over-the-Wire)	
Manufacturer	Boston Scientific Corporation
Number	P100023/S015
Filing Date	7/15/2011
Approval Date	2/22/2012
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	222
Total Review Days	222
BreathTek UBT FOR H. pylori Kit and Pediatric Urea Hydrolysis Rate Calculation Application (pUHR-CA), Version 1.0	
Manufacturer	Otsuka America Pharmaceutical, Inc.
Number	P100025
Filing Date	6/22/2010
Approval Date	2/22/2012
Approved, Labeled Pediatric Subpopulation:	3-17
Exempt from User Fees because intended solely for pediatric use?	Yes
FDA Review Days	170
Total Review Days	610
ADVIA Centaur HBeAg ASSAY and Quality Control Material - a laboratory test used to detect human hepatitis Be antigen (HBeAg) in a person with a hepatitis B virus (HBV) infection.	
Manufacturer	Siemens Healthcare Diagnostics
Number	P090024
Filing Date	10/22/2009
Approval Date	10/11/2011
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	306
Total Review Days	719

PMA Device Information	
ADVIA Centaur Anti-HBs2 (aHBs2) Assay and Quality Control Material - a laboratory test used to detect antibodies associated with hepatitis B virus (HBV) infection.	
Manufacturer	Siemens Healthcare Diagnostics
Number	P100039
Filing Date	10/4/2010
Approval Date	1/20/2012
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	161
Total Review Days	473
APTIMA HPV Assay - used with the TIGRIS® DTS ® System to identify human papillomavirus (HPV)	
Manufacturer	Gen-Probe Incorporated
Number	P100042
Filing Date	11/5/2010
Approval Date	10/28/2011
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	175
Total Review Days	357
ARCHITECT HBsAg Qualitative, Qualitative Confirmatory, Confirmatory Manual Diluent, Calibrators, and Controls - used with the Abbott ARCHITECT Instrument System to identify certain virus proteins associated with hepatitis B virus (HBV)	
Manufacturer	Abbott Laboratories
Number	P110029
Filing Date	7/26/2011
Approval Date	4/12/2012
Approved, Labeled Pediatric Subpopulation:	All Ages
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	179
Total Review Days	261
HDE Device Information	
Berlin Heart EXCOR® Pediatric Ventricular Assist Device (VAD)	
Manufacturer	Berlin Heart, Inc.
Number	H100004
Filing Date	6/22/2010
Approval Date	12/16/2011
Approved, Labeled Pediatric Subpopulation:	All Ages with size limitations
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	405
Total Review Days	546

[i] http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089274.htm

[ii] http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm389275.pdf