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Client Alert

FDA & Life Sciences Practice Group

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FDA Issues Supplemental Notice of Proposed Rulemaking and Draft Guidance Regarding Inclusion of Pediatric Subpopulation Information in Certain Medical Device Submissions

On February 19, 2013, FDA issued a supplemental notice of proposed rulemaking in the *Federal Register*, re-proposing amendments regarding information about pediatric subpopulations that must be submitted for certain medical device applications (Docket No. FDA–2009–N–0458).[i] The Food and Drug Administration Amendments Act of 2007 (FDAAA) added section 515A to the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360e-1), which requires certain medical device submissions 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. To implement this provision, FDA initially published a proposed rule and a companion direct final rule in the Federal Register in April 1, 2010. However, FDA withdrew the direct final rule in light of significant adverse comments received in response to it.

FDA made changes since the April 1, 2010 proposed rule, and accordingly, issued the notice of proposed rulemaking to allow for public comment on the re-drafted proposed rule. The notice of proposed rulemaking indicates that the requirement to submit readily available information about pediatric subpopulations applies to the following submission types, when submitted on or after the effective date of the rule: (1) any request for a humanitarian device exemption (HDE) submitted under section 520(m) of the FDCA; (2) any premarket approval application (PMA) or supplement to a PMA submitted under section 515 of the FDCA; and (3) any product development protocol (PDP) submitted under section 515 of the FDCA.

If an applicant fails to submit readily available information on pediatric subpopulations, FDA may not approve the application until the information is provided. If the application has no other deficiencies, FDA plans to send an "approvable" letter to the applicant, indicating that the application will be approved when the readily available information on pediatric subpopulations is submitted.

Written or electronic comments on the proposed rule are due by April 22, 2013.

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Along with this notice of proposed rulemaking, FDA issued a draft guidance titled "Providing Information about Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act."[ii], which describes how to compile and submit readily available information on pediatric subpopulations. The draft guidance clarifies that "readily available information" is information that is available in the public domain, "through commonly used public resources for conducting biomedical, regulatory, and medical product research." Reliable sources of information in the public domain include:

- Original research reports published in peer-reviewed medical and scientific journals;
- Federal, state or local government sources of vital statistics and disease frequency data;
- Systematic research syntheses such as those available on the Cochrane Database of Systematic Reviews;
- Complete previous research study results available on clinicaltrials.gov;
- Premarket pivotal trial data (if data are publicly available);
- Professional society registry data;
- Administrative and clinical databases (*e.g.*, Hospital Discharge Data); and
- Large surveys (*e.g.*, National Emergency Injury Surveillance System, National Survey of Children's Health).

According to the draft guidance, "unacceptable data sources" include: internal marketing tracking; sales records; research and development reports; consultations with pediatric experts; and unpublished presentations from major professional meetings. The draft guidance also clarifies that readily available information submitted about pediatric device use should not include proprietary, trade secret, and commercial confidential information about the device.

The pediatric subpopulations about which readily available information must be submitted are defined in the draft guidance as follows: Neonates (birth through the first 28 days of life), Infants (day 29 to less than 2 years of age), Children (age 2 to less than 12 years of age), and Adolescents (age 12 through 21 years of age, up to, but not including, the twenty-second birthday).

Pediatric subpopulation information should be submitted in a separate section of the submission titled, "515A Pediatric Device Use Information." The draft guidance provides a summary table containing an example of the information that should be presented for each proposed indication for the device: pediatric incidence and prevalence of the disease or condition that the device is intended to treat diagnose, or cure; the specific pediatric subpopulation affected; the specific device or component; and the source of the information. The draft guidance specifies that providing only the pediatric subpopulation information described in section 515A of the FDCA is not sufficient to establish the safety and effectiveness of a device for a new pediatric indication.

As required by section 515A of the FDCA, the Secretary of Health and Human Services will submit an annual report on pediatric subpopulation information to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce. The annual report will indicate the number of devices approved in the prior year for which there is a pediatric subpopulation that suffers from a disease or condition that the device is intended to treat, diagnose, or cure. FDA will include section 515A pediatric subpopulation information in its annual report to Congress. FDA ultimately plans to use the data to better coordinate the promotion of new device development for unmet pediatric needs and to ensure appropriate labeling of existing devices for pediatric use.

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If you have any questions regarding the attached notice or the draft guidance document or want our assistance in preparing comments on them, please contact us.

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[i] *Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended to Treat, Diagnose, or Cure, 78 Federal Register 11,612 (Feb. 19, 2013).*

[ii] *Guidance for Industry and Food and Drug Administration Staff: Providing Information about Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act, 78 Federal Register 11,654 (Feb. 19, 2013). See http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM339465.pdf.*