OFFICE OF THE CENTER DIRECTOR

Public Dissemination of a Summary of the Medical and Clinical Pharmacology Reviews of Pediatric Studies

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PURPOSE

- This MAPP describes for the Offices and Divisions in the Center for Drug Evaluation and Research (CDER)

  - the requirements of section 9 of the Best Pharmaceuticals for Children Act (BPCA) and

  - the policies and procedures in CDER for preparing and disseminating summaries of the medical and the clinical pharmacology and biopharmaceutics reviews of pediatric studies submitted in response to a Written Request.

BACKGROUND

- On January 4, 2002, the President signed into law the Best Pharmaceuticals for Children Act (BPCA). This legislation reauthorizes and amends the exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the Act).

- Under section 9 of the BPCA, FDA is required to make available to the public a summary of both the medical and clinical pharmacology reviews of pediatric studies conducted for supplements submitted in response to a Written Request no later than 180 days from the date of submission (i.e., date received by CDER) of a pediatric study report (section 505A(m)(1) of the Act).

REFERENCES

- Federal Food, Drug, and Cosmetic Act
- Best Pharmaceuticals for Children Act, Section 9
- Freedom of Information Act
- MAPP 4000.4 Clinical Pharmacology and Biopharmaceutics Review Template
- MAPP 6010.3 Clinical Review Template
- MAPP 6020.8 Action Packages for NDAs and Efficacy Supplements

DEFINITIONS

- **Pediatric Study Report:** Final pediatric study (or studies) submitted to the Agency as a supplement to an approved new drug application that is either a complete or an incomplete response to a Written Request.

- **CDER's Drug Approval Web page (Drugs @ FDA):** http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm

- **CDER's Pediatric Web page:** http://www.fda.gov/cder/pediatric

POLICY

- CDER will fulfill the requirements of section 9 of the BPCA by
  - creating summaries of the medical and clinical pharmacology reviews,
  - making the summaries available to the public on the Pediatric Web page, and
  - announcing the availability of the summaries in the *Federal Register*.

- The Agency will provide summaries for **approval, approvable,** and **not approvable** actions on pediatric supplements that have been **filed**.

- This policy applies to all supplements submitted in response to a Written Request, whether or not the submitted pediatric study reports constitute a complete response to the Written Request.

- The Executive Summaries created with the Clinical Review Template and the Clinical Pharmacology and Biopharmaceutics Review Template will serve as the summaries of medical and pharmacology reviews that will made available for public dissemination under section 9 of the BPCA. (CDER uses the term *clinical review* instead of the term *medical review* used in the BPCA.)

- The period "no later than 180 days from the date of submission" referred to in the BPCA is interpreted to mean the 6-month PDUFA goal date that applies to all pediatric supplements submitted in response to a Written Request.

- These summaries are not required for NDAs or for pediatric supplements that are **not** submitted in response to a Written Request.

RESPONSIBILITIES AND PROCEDURES

The Review Divisions will:

- Generate Executive Summaries of the clinical review and clinical pharmacology review for all supplements submitted in response to a Written Request.

    - Create the Executive Summaries using the Clinical Review Template and the Clinical Pharmacology and Biopharmaceutics Review Template.

    - Consider the following points pertaining to the public release of information when preparing the summaries. This list is not exhaustive, and adherence to this list is not a substitute for review by the Division of Information Disclosure Policy (DIDP) prior to releasing information to the public. The following information should not be included in the summary if it can be avoided:

        — References to indications not approved, except for the pediatric indication being considered

        — Distribution, use, or sales data received from the company or alternative sources

        — Identifiers of participants in clinical trial(s), including subinvestigators. Principal investigators may be identified.

        — Information about a company other than the applicant (e.g., supplier, Drug Master File holder)

        The information listed above should not be used in footers and document names.

- Enter each of the final completed and signed off Executive Summaries into the Division File System (DFS) as a BPCA Summary Review by close of business Day 175.

    - If the signatory authority (generally the Division Director or designee) concurs with the Executive Summary of the review, the Executive Summary will be entered into DFS as the BPCA Summary Review. This may be done by either the Division Director or designee.

    - If the signatory authority disagrees with anything in the Executive Summary, the Executive Summary will be revised accordingly, then entered into DFS as the BPCA Summary Review.

    - Executive Summaries are entered into DFS as BPCA Summary Reviews by choosing:

        a. Division Document Type: Forms
        b. Form Group: Administrative
        c. Form Name: BPCA Summary Review

    - By entering the Executive Summaries into DFS as the BPCA Summary Reviews, the DIDP project manager and the DIDP e-mail distribution list will be automatically copied, as well as the Chief, Project Management Staff (CPMS) (HFD-960), in the Division of Pediatric Drug Development (DPDD).

DIDP (HFD-013) will:

- Redact the summaries prepared by the review division to ensure compliance with information disclosure regulations and statutes before the summaries are made available to the public.

- Within 3 calendar days of receipt of the summaries, forward each redacted summary electronically to the Division of Library and Information Services (DLIS) for posting, noting that this document must be posted within 2 calendar days to comply with the 180-day time frame stipulated in the BPCA.

- Alert the CPMS in HFD-960 that the documents have been forwarded to the DLIS.

OTCOM/DLIS (HFD-230) will:

- If the action taken is an **approval**, post the summaries on the Internet on CDER's Drug Approval page, and create a hyperlink to CDER's Pediatric Web page.

- If the action taken is an **approvable** or **not approvable**, post the summaries only on CDER's Pediatric Web page upon notification from the DPDD that an action has been taken.

- Create a hyperlink from the notice of availability (NOA) to the drug name posted on the Pediatric Web page.

DPDD (HFD-960) will:

- Inform OTCOM/LIS that action has been taken on the supplement and that the summary(s) may be posted on the Web.

- Check to confirm that the redacted summary has been posted.

- Prepare an NOA based on the template attached to this MAPP.

- Coordinate with the Office of Regulatory Policy (ORP) for publication in the *Federal Register* of an NOA for the summaries of each drug to be posted.

- Notify OTCOM/LIS of the publication of the NOA.

- Ensure that the NOA has been hyperlinked to the drug summary posted on the Pediatric Web page.

ORP (HFD-007) will:

- After receiving the NOA from DPDD, prepare the NOA for clearance.

- Submit the NOA for clearance to:
    - Director of Division of Regulatory Policy
    - Director of Division of Pediatric Drug Development
    - Director of Office of New Drugs (FYI only)
    - Director of Division of Information Disclosure Policy (FYI only)
    - Director of Office of Counter Terrorism and Pediatric Drug Development

- Associate Director for Policy
- Deputy Director for the Center for Drug Evaluation and Research
- Director for the Center for Drug Evaluation and Research
- Regulatory Policy and Management Staff

- Notify the Division of Drug Information and the Office of Chief Counsel when the NOA has been sent for publication.[1]

EFFECTIVE DATE

This MAPP is effective upon date of publication.

[1] The attached template was cleared by the Office of Chief Counsel (OCC). Therefore, OCC review of NOAs based on the template is not necessary (per 11/20/2003 e-mail from Kim Dettelbach to Aileen Ciampa).

Attachment A

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for [INSERT DRUG NAME]. The summaries are being made available consistent with section 9 of the Best Pharmaceuticals for Children Act (BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

ADDRESSES: Submit written requests for single copies of the summaries to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or summaries you are requesting. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the summaries.

FOR FURTHER INFORMATION CONTACT:

Grace Carmouze,

Center for Drug Evaluation and Research (HFD-960),

Food and Drug Administration,

5600 Fishers Lane,

Rockville, MD 20857,

301-594-7337,

carmouzeg@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for [INSERT DRUG NAME]. The summaries are being made available consistent with section 9 of the BPCA (Public Law 107-109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Section 505A permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21 U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this provision of the BPCA, FDA has posted on the Internet (http://www.fda.gov/cder/pediatric/index.htm) summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for [INSERT DRUG NAME]. Copies are also available by mail (see ADDRESSES).

II. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/pediatric/index.htm.

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Dated:_____

COMIS # _____ FRDTS # CDER_____

Drafted: