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SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when the PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from Close Care Gap, PSO, a component entity of iCareQuality, Inc., PSO number P0145, to voluntarily relinquish its status as a PSO. Accordingly, Close Care Gap, PSO was delisted effective at 12:00 Midnight ET (2400) on July 2, 2015.

More information on PSOs can be obtained through AHRQ's PSO Web site at <http://www.pso.AHRQ.gov/index.html>.

Sharon B. Arnold,
Deputy Director.

[FR Doc. 2015-20597 Filed 8-19-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS)

announces the following meeting of the aforementioned committee.

TIMES AND DATES:

11:00 a.m.-5:30 p.m., September 24, 2015.

8:30 a.m.-1:00 p.m., September 25, 2015.

PLACE: NCHS Headquarters, 3311 Toledo Road, Hyattsville, Maryland 20782.

STATUS: This meeting is open to the public; however, visitors must be processed in accordance with established federal policies and procedures. For foreign nationals or non-U.S. citizens, pre-approval is required (please contact Gwen Mustaf, 301-458-4500, glm4@cdc.gov, or Virginia Cain, vcain@cdc.gov at least 10 days in advance for requirements). All visitors are required to present a valid form of picture identification issued by a state, federal or international government. As required by the Federal Property Management Regulations, Title 41, Code of Federal Regulation, Subpart 101-20.301, all persons entering in or on Federal controlled property and their packages, briefcases, and other containers in their immediate possession are subject to being x-rayed and inspected. Federal law prohibits the knowing possession or the causing to be present of firearms, explosives and other dangerous weapons and illegal substances. The meeting room accommodates approximately 100 people.

PURPOSE: This committee is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

MATTERS FOR DISCUSSION: The agenda will include:

1. Welcome remarks by the Director, NCHS
2. An update on health insurance coverage data
3. A presentation on the National Health and Nutrition Examination Survey (NHANES) and the development of nutritional guidelines
4. A presentation on accessing NCHS data

Requests to make oral presentations should be submitted in writing to the contact person listed below. All requests must contain the name, address, telephone number, and organizational affiliation of the presenter.

Written comments should not exceed five single-spaced typed pages in length

and must be received by September 11, 2015.

The agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION:

Virginia S. Cain, Ph.D., Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7208, Hyattsville, Maryland 20782, telephone (301) 458-4500, fax (301) 458-4024.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Management Analysis and Services Office,
Centers for Disease Control and Prevention.

[FR Doc. 2015-20553 Filed 8-19-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Pediatric Advisory Committee; Notice of Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of August 12, 2015 (80 FR 48325). Phenylephrine Hydrochloride was incorrectly linked to DUREZOL (difluprednate ophthalmic emulsion) 0.05% because they were both listed as item number 1 in the numbered list of products to be discussed at the meeting. Phenylephrine Hydrochloride Ophthalmic Solution is a separate stand-alone drug that will be reviewed by the committee and should be listed as item number 2. The other drugs in the numbered list should be renumbered accordingly. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Planning, Legislation, and Analysis, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

SUPPLEMENTARY INFORMATION: In FR Doc. 2015-19729, appearing on page 48325, in the **Federal Register** of Wednesday, August 12, 2015, the following correction is made:

On page 48326, in the first column, the numbered list is corrected to read as follows:

1. DUREZOL (difluprednate ophthalmic emulsion) 0.05%,
2. Phenylephrine Hydrochloride Ophthalmic Solution,
3. ZYLET (loteprednol etabonate and tobramycin ophthalmic suspension),
4. BETHKIS (tobramycin Inhalation Solution),
5. INTELENCE (etravirine),
6. PREZISTA (darunavir),
7. VIRAMUNE XR (nevirapine),
8. EPIDUO (adapalene and benzoyl peroxide),
9. EXJADE (deferiasirox),
10. DOTAREM (gadoterate meglumine),
11. FYCOMPA (perampanel),
12. RECOTHROM (thrombin, topical [recombinant]),
13. PREVNAR 13 (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM₁₉₇ Protein]),
14. PLEXIMMUNE,
15. ELANA SURGICAL KIT (HUD),
16. BERLIN HEART EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE (VAD),
17. ENTERRA THERAPY SYSTEM, and
18. CONTEGRA Pulmonary Valved Conduit.

Dated: August 14, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015-20541 Filed 8-19-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2986]

Technical Document for Using the Inactive Ingredient Database; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA, or the Agency) is announcing the establishment of a public docket to receive comments from interested parties on enhancing the utility and usability of the Inactive Ingredient Database (IID) (also known as the Inactive Ingredient Guide). These comments will help FDA identify best practices to assist Agency staff in designing the IID and maintaining the information contained therein. We

intend to identify and further develop these best practices in a technical guide or draft guidance to be issued at a later date.

DATES: Submit either electronic or written comments by October 19, 2015.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993-0002, 240-402-7930.

SUPPLEMENTARY INFORMATION:

I. Background

The IID provides information on inactive ingredients in FDA-approved drug products. An inactive ingredient, or excipient, is any component of a drug product other than an active ingredient (21 CFR 210.3(b)(8)). Generally, the IID identifies excipients that appear in approved drug products for a particular dosage form and route of administration.

In September 2011, FDA created the IID Working Group to develop a set of questions and answers to facilitate use of the IID. During the development of questions and answers, FDA has worked with the International Pharmaceutical Excipients Council (IPEC Americas).¹ FDA is opening a public docket to solicit comments from additional stakeholders on enhancing the utility and usability of the IID. FDA will then develop a comprehensive technical guide or draft guidance for industry and reviewers.

II. Establishment of a Public Docket and Request for Comments

To help FDA identify and ultimately establish best practices and issue a technical guide or draft guidance, FDA is requesting public comments regarding the enhancement of the IID.

FDA is requesting comments and supporting information, including proposed questions and proposed answers, on the following topics related to the IID:

1. How can we improve nomenclature in the IID (e.g., use of preferred ingredient names and synonyms in the database)?

2. How should we identify excipient amounts listed in the IID?

3. How should we reflect updates to the current IID to ensure completeness and accuracy?

4. Should we restructure the IID, and if so, how?

5. Are there additional suggestions or comments for IID improvement?

FDA will consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the comment.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: August 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-20556 Filed 8-19-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2099]

Lisa Marie Coroniti: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarment Lisa Coroniti from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Coroniti was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Ms. Coroniti was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Ms. Coroniti failed to request a hearing.

¹ See Meetings between FDA and the International Pharmaceutical Excipients Council (IPEC), available at <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtoxicology/ucm380688.htm>.