

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
November 3, 2016

AGENDA

During the morning session, the committee will discuss three bulk drug substances nominated for inclusion on the list of bulk drug substances that can be used to compound drugs in accordance with section 503A of the Food, Drug, and Cosmetic Act (FD&C Act): glycolic acid, trichloroacetic acid, and kojic acid.

November 3, 2016, AM Session

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| 8:30 a.m. | Call to Order and Introduction of Committee | Padma Gulur, MD
Acting Chairperson, PCAC |
| 8:35 a.m. | Conflict of Interest Statement | Cindy Hong, PharmD
Designated Federal Officer, PCAC |
| 8:40 a.m. | FDA INTRODUCTORY REMARKS | Emily Gebbia, JD
Senior Advisor
Office of Compliance, CDER |
| 8:45 a.m. | 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS | |
| | <i>Glycolic Acid</i> | Jane Liedtka, MD
Clinical Reviewer
Division of Pediatrics and Maternal Health
Office of Drug Evaluation (ODE) IV
Office of New Drugs (OND), CDER |
| | Clarifying Questions from the Committee | |
| | NOMINATOR PRESENTATIONS | John Voliva, RPh
International Academy of Compounding
Pharmacists (IACP) |
| | Clarifying Questions from the Committee | |
| 9:25 a.m. | OPEN PUBLIC HEARING | |
| 9:35 a.m. | COMMITTEE DISCUSSION AND VOTE | |
| 9:45 a.m. | 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.) | |
| | <i>Trichloroacetic Acid</i> | Roselyn E. Epps, MD
Clinical Reviewer
Division of Dermatology and Dental Products
ODE III, OND, CDER |
| | Clarifying Questions from the Committee | |

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AGENDA (cont.)

NOMINATOR PRESENTATIONS

A.J. Day, PharmD

Professional Compounding Centers of America
(PCCA)

Clarifying Questions from the Committee

10:25 a.m. **OPEN PUBLIC HEARING**

10:35 a.m. **COMMITTEE DISCUSSION AND VOTE**

10:45 a.m. **BREAK**

11:00 a.m. **503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**

Kojic Acid

Jonathan Jarow, MD

Senior Medical Advisor
Office of the Center Director, CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Tom Wynn, RPh

Fagron

Clarifying Questions from the Committee

11:40 a.m. **OPEN PUBLIC HEARING**

11:50 a.m. **COMMITTEE DISCUSSION AND VOTE**

12:00 p.m. **LUNCH**

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AGENDA (cont.)

During the afternoon session, the committee will discuss two additional bulk drug substances nominated for inclusion on the list of bulk drug substances that can be used to compound drugs in accordance with section 503A of the FD&C Act: diindolylmethane and vasoactive intestinal peptide. The committee will also discuss the following drug products, which were nominated as drug products that present demonstrable difficulties for compounding and that cannot be compounded under sections 503A and 503B of the FD&C Act: drug products that employ transdermal or topical delivery systems (TDS).

November 3, 2016, PM Session

1:00 p.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**

Diindolylmethane

Michael Brave, MD
Medical Officer
Division of Oncology Products 1
Office of Hematology and Oncology Products (OHOP)
OND, CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

A.J. Day, PharmD
PCCA

Clarifying Questions from the Committee

1:45 p.m. **OPEN PUBLIC HEARING**

1:55 p.m. **COMMITTEE DISCUSSION AND VOTE**

2:05 p.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**

Vasoactive Intestinal Peptide

Susan Johnson, PharmD, PhD
Associate Director
Office of Drug Evaluation IV, OND, CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Ritchie Shoemaker, MD
Hopkinton Drug Inc.

Clarifying Questions from the Committee

2:50 p.m. **OPEN PUBLIC HEARING**

3:00 p.m. **COMMITTEE DISCUSSION AND VOTE**

3:10 p.m. **BREAK**

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting
November 3, 2016

AGENDA (cont.)

- 3:20 p.m. Conflict of Interest Statement **Cindy Hong, PharmD**
- 3:25 p.m. **DEMONSTRABLY DIFFICULT TO
COMPOUND — DRUG PRODUCTS THAT
EMPLOY TRANSDERMAL OR TOPICAL
DELIVERY SYSTEMS PRESENTATIONS** **Caroline Strasinger, PhD**
Office of New Drugs
Office of Pharmaceutical Quality, CDER
- Clarifying Questions from the Committee
- NOMINATOR PRESENTATIONS**
- Clarifying Questions from the Committee
- 4:10 p.m. **OPEN PUBLIC HEARING**
- 4:20 p.m. **COMMITTEE DISCUSSION AND VOTE**
- 4:30 p.m. **ADJOURNMENT**