

Food and Drug Administration
Center for Drug Evaluation and Research

Summary Minutes of the Pharmacy Compounding Advisory Committee Meeting

November 3, 2016

Location: FDA White Oak Campus, Building 31 Conference Center, The Great Room (Rm. 1503), Silver Spring, Maryland

Topic: On November 3, 2016, the committee discussed five bulk drug substances nominated for inclusion on the section 503A bulk drug substances list. FDA discussed the following nominated bulk drug substances: glycolic acid, trichloroacetic acid, kojic acid, diindolylmethane, and vasoactive intestinal peptide. The nominators of these substances were invited to make a short presentation supporting the nomination. During the afternoon session, the committee also discussed drug products that employ transdermal or topical delivery systems, which were nominated for the Difficult to Compound List.

These summary minutes for the November 3, 2016 meeting of the Pharmacy Compounding Advisory Committee of the Food and Drug Administration were approved on 12/2/16.

I certify that I attended the November 3, 2016 meeting of the Pharmacy Compounding Advisory Committee and that these minutes accurately reflect what transpired.

_____/s/_____
Cindy Hong, PharmD
Designated Federal Officer
Pharmacy Compounding
Advisory Committee (PCAC)

_____/s/_____
Padma Gulur, MD
Acting Chairperson, PCAC

Summary Minutes of Meeting of the Pharmacy Compounding Advisory Committee November 3, 2016

The following is a final report of the Pharmacy Compounding Advisory Committee (PCAC) meeting held on November 3, 2016. A verbatim transcript will be available in approximately six weeks, sent to the Office of Compliance, to the Agency Lead on Pharmacy Compounding and posted on the FDA website at:

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/ucm486094.htm>

All external requests for the meeting transcripts should be submitted to the CDER Freedom of Information Office.

The Pharmacy Compounding Advisory Committee (PCAC) of the Food and Drug Administration, Center for Drug Evaluation and Research met on November 3, 2016 from 8:30 a.m. until 4:30 p.m., at the FDA White Oak Campus, Building 31 Conference Center, The Great Room (Rm. 1503), Silver Spring, Maryland. Prior to the meeting, members and temporary voting members were provided copies of the briefing materials from the FDA. The meeting was called to order by Padma Gulur, MD (Acting Chairperson); the conflict of interest statement was read into the record by Cindy Hong, PharmD (Designated Federal Officer). There were approximately 40 persons in attendance in the audience section. There were four (4) Open Public Hearing presentations.

Issue:

On November 3, 2016, the committee discussed five bulk drug substances nominated for inclusion on the section 503A bulk drug substances list. FDA discussed the following nominated bulk drug substances: glycolic acid, trichloroacetic acid, kojic acid, diindolylmethane, and vasoactive intestinal peptide. The nominators of these substances were invited to make a short presentation supporting the nomination. During the afternoon session, the committee also discussed drug products that employ transdermal or topical delivery systems, which were nominated for the Difficult to Compound List.

Attendance:

PCAC Members Present (Voting):

Michael Carome, MD, FACP (Consumer Representative) (all topics except transdermal or topical delivery systems); Gigi Davidson, BPh, DICVP (US Pharmacopeial Convention Representative); John DiGiovanna, MD; Padma Gulur, MD (Acting Chairperson); Stephen Hoag, PhD; Katherine Pham, PharmD, BCPS; Allen Vaida, BSc, PharmD, FASHP; Donna Wall, PharmD (National Association of Boards of Pharmacy Representative)

PCAC Members Present (Non-Voting): Ned Braunstein, MD (Industry Representative); William Mixon, RPh, MS, FIACP (Industry Representative)

PCAC Members Not Present (Voting): William Humphrey, BPharm, MBA, MS; Jürgen Venitz, MD, PhD

Temporary Members (Voting): Antonio Fojo, MD, PhD (diindolylmethane topic only)

FDA Participants (Non-Voting): Michael Brave, MD; Frances Gail Bormel, RPh, JD; Roselyn Epps, MD; James Flahive, JD; Charles Ganley, MD; Emily Gebbia, JD; Jonathan Jarow, MD; Susan Johnson, PharmD, PhD; Hon-Sum Ko, MD; Rosilend Lawson, VMD, JD; Jane Liedtka, MD; Caroline Strasinger, PhD

Designated Federal Officer (Non-Voting): Cindy Hong, PharmD

Open Public Hearing Speakers:

A.J. Day, PharmD, RPh (Professional Compounding Centers of America); Seemal Desai, MD, FAAD (American Academy of Dermatology Association and American Society for Dermatologic Surgery Association)

The agenda proceeded as follows:

November 3, 2016 a.m. session:

Call to Order and Introduction of Committee

Padma Gulur, MD
Acting Chairperson, PCAC

Conflict of Interest Statement

Cindy Hong, PharmD
Designated Federal Officer, PCAC

FDA INTRODUCTORY REMARKS

Emily Gebbia, JD
Senior Advisor
Acting Agency Lead on Compounding
Office of Compliance, CDER

503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS

Glycolic Acid

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

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)

Trichloroacetic Acid

Roselyn E. Epps, MD
Clinical Reviewer
Division of Dermatology and Dental Products
ODE III, OND, CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

A.J. Day, PharmD
Professional Compounding Centers of America
(PCCA)

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

BREAK

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

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

LUNCH

November 3, 2016 p.m. session

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,
OND, CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

A.J. Day, PharmD
PCCA

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)

Vasoactive Intestinal Peptide

Susan Johnson, PharmD, PhD
Associate Director
ODE IV, OND, CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Ritchie Shoemaker, MD
Hopkinton Drug Inc.

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

BREAK

Conflict of Interest Statement

Cindy Hong, PharmD

**DEMONSTRABLY DIFFICULT TO COMPOUND —
DRUG PRODUCTS THAT EMPLOY TRANSDERMAL OR
TOPICAL DELIVERY SYSTEMS PRESENTATIONS**

Caroline Strasinger, PhD
OND, Office of Pharmaceutical Quality,
CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

ADJOURNMENT

Questions to the Committee:

November 3, 2016, a.m. session

**Questions for PCAC Regarding Whether to Include Certain Bulk Drug Substances
on the 503A Bulk List**

1. FDA is proposing that glycolic acid, up to 70%, for topical use be INCLUDED on the 503A Bulks List. Should glycolic acid be placed on the list?

YES: 8 NO: 0 ABSTAIN: 0

Committee Discussion: *The committee unanimously agreed that glycolic acid should be placed on the 503A Bulks List for topical use only. Members commented on its safe and efficacious use in other countries and believed it could be used safely with expert supervision. Please see the transcript for details of the committee discussion.*

2. FDA is proposing that trichloroacetic acid for topical use be INCLUDED on the 503A bulk list. Should trichloroacetic acid be placed on the list?

YES: 7 NO: 1 ABSTAIN: 0

Committee Discussion: *A majority of the committee agreed that trichloroacetic acid should be placed on the 503A Bulks List. The members commented on its wide spread use and saw no significant safety concerns; hence, they believed it could be used safely as an alternate agent when first-line agents fail. The member who voted "NO" commented on the lack of efficacy data and the availability of other products. Please see the transcript for details of the committee discussion.*

3. FDA is proposing that kojic acid NOT be included on the 503A Bulks List. Should kojic acid be placed on the list?

YES: 3 NO: 4 ABSTAIN: 1

Committee Discussion: *A slight majority of the committee agreed that kojic acid should not be placed on the 503A Bulks List. Members commented on the lack of evidence for efficacy and the presence of a safety risk. They also expressed concerns with the instability of the drug. Member that voted "YES" commented that the drug is efficacious for some patients and that stability issues can be addressed. Please see the transcript for details of the committee discussion.*

November 3, 2016, p.m. session

Questions for PCAC Regarding Whether to Include Certain Bulk Drug Substances on the 503A Bulk List

1. FDA is proposing that that diindolylmethane NOT be included on the 503A Bulks List. Should diindolylmethane be placed on the list?

YES: 1 NO: 8 ABSTAIN: 0

***Committee Discussion:** The majority of the committee agreed that diindolylmethane should not be placed on the 503A Bulks List. The one member who voted "YES" commented that the drug did not have a safety signal and appears to be effective in modulating estrogen metabolism, and a compounding pharmacy would be a reliable place for patients to obtain the drug substance. Members that voted "NO" expressed that there was no clear benefit to diindolylmethane use. Please see the transcript for details of the committee discussion.*

2. FDA is proposing that vasoactive intestinal peptide NOT be included on the 503A Bulks List. Should vasoactive intestinal peptide be placed on the list?

YES: 0 NO: 8 ABSTAIN: 0

***Committee Discussion:** The committee unanimously agreed that vasoactive intestinal peptide should not be placed on the 503A Bulks List. Members commented on the need for more data and that an Investigational New Drug (IND) application should be submitted for its use. Please see the transcript for details of the committee discussion.*

Question for PCAC Regarding Whether to Include Certain Drug Products or Categories of Drug Products on the Difficult to Compound List

3. FDA is proposing that drug products that employ transdermal or topical delivery systems be INCLUDED on the Difficult to Compound List under sections 503A and 503B of the FD&C Act. Should drug products that employ transdermal or topical delivery systems be placed on the list?

YES: 7 NO: 0 ABSTAIN: 0

***Committee Discussion:** The committee unanimously agreed that drug products that employ transdermal or topical delivery systems should be placed on the Difficult to Compound List under sections 503A and 503B of the FD&C Act. Please note that the one member who had originally voted "NO" subsequently noted into the record during the explanation of the vote that he meant to vote "YES." The record was corrected to reflect a "YES" vote. The vote count above records his vote as "YES." Please see the transcript for details of the committee discussion.*

The meeting was adjourned at approximately 3:50 p.m.