

Food and Drug Administration
Center for Drug Evaluation and Research

Summary Minutes of the Pharmacy Compounding Advisory Committee Meeting

June 23, 2016

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

Topic: On June 23, 2016, the committee discussed six bulk drug substances nominated for inclusion on the section 503A bulk drug substances list. FDA intends to discuss the following nominated bulk drug substances: Chrysin, cesium chloride, sodium dichloroacetate, pyruvic acid, tea tree oil, and 2,3-Dimercapto-1-propanesulfonic acid (DMPS). The nominators of these substances were invited to make a short presentation supporting the nomination. During the afternoon session, the committee received updates on certain issues to follow up on discussions from previous meetings, including the option for obtaining access to investigational new drugs under expanded access.

These summary minutes for the June 23, 2016 meeting of the Pharmacy Compounding Advisory Committee of the Food and Drug Administration were approved on August 3, 2016__.

I certify that I attended the June 23, 2016 meeting of the Pharmacy Compounding Advisory Committee and that these minutes accurately reflect what transpired.

_____/s/_____
Cindy Hong, PharmD
Designated Federal Officer
Pulmonary-Allergy Drugs
Advisory Committee (PCAC)

_____/s/_____
Jürgen Venitz, MD, PhD
Chairperson, PCAC

**Summary Minutes of Meeting of the Pharmacy Compounding Advisory Committee
June 23, 2016**

The following is the final report of the Pharmacy Compounding Advisory Committee (PCAC) meeting held on June 23, 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 June 23, 2016 from 8:30 a.m. until 5:00 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 Jürgen Venitz, MD, PhD (Chairperson); the conflict of interest statement was read into the record by Cindy Hong, PharmD (Designated Federal Officer). There were approximately 70 persons in attendance in the audience section. There were three (3) Open Public Hearing presentations.

Issue:

On June 23, 2016, the committee discussed six bulk drug substances nominated for inclusion on the section 503A bulk drug substances list. FDA discussed the following nominated bulk drug substances: chrysin, cesium chloride, sodium dichloroacetate, pyruvic acid, tea tree oil, and 2,3-Dimercapto-1-propanesulfonic acid (DMPS). The nominators of these substances were invited to make a short presentation supporting the nomination. During the afternoon session, the committee received updates on certain issues raised in previous meetings, including the option for obtaining access to an investigational new drug (IND) under an expanded access IND application.

Attendance:

PCAC Members Present (Voting):

Michael Carome, MD (Consumer Representative) (all topics except DMPS); Gigi Davidson, BScPh, DICVP (USP Representative); John DiGiovanna, MD; Padma Gulur, MD; Stephen Hoag, PhD; William Humphrey, BS Pharm, MBA; Elizabeth Jungman, JD; Katherine Pham, PharmD; Allen Vaida, PharmD; Jürgen Venitz, MD, PhD (Chairperson); Donna Wall, PharmD (NABP Representative)

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

PCAC Member Not Present (Voting): None

Temporary Members (Voting): Jeffrey Brent, MD, PhD (DMPS only)

FDA Participants (Non-Voting): Michael Brave, MD; Frances Gail Bormel, RPh, JD; Brenda Carr, MD; Julie Dohm, JD, PhD; James Flahive, JD; Charles Ganley, MD; Emily Gebbia, JD; Jonathan Jarrow, MD; Hon-Sum Ko, MD; Kathy Robie Suh, MD, PhD

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

Open Public Hearing Speakers:

A.J. Day, PharmD, RPh (Professional Compounding Centers of America); Ronna Hauser, PharmD (National Community Pharmacists Association); Ronald McGuff (McGuff Compounding Pharmacy)

The agenda proceeded as follows:

June 23, 2016 a.m. session:

Call to Order and Introduction of Committee

Jürgen Venitz, MD, PhD
Chairperson, PCAC

Conflict of Interest Statement

Cindy Hong, PharmD
Designated Federal Officer, PCAC

FDA INTRODUCTORY REMARKS

Julie Dohm, JD, PhD
Senior Science Advisor for Compounding,
CDER

503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS

Chrysin

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

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Tom Wynn, RPh
Fagron

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

June 23, 2016
Meeting of the Pharmacy Compounding Advisory Committee

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

Cesium Chloride

Michael Brave, MD

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Paul Anderson, ND
American Association of Naturopathic
Physicians (AANP)

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

BREAK

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

Sodium Dichloroacetate

Michael Brave, MD

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Paul Anderson, ND

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

LUNCH

June 23, 2016 p.m. session

**EXPANDED ACCESS TO INVESTIGATIONAL NEW
DRUGS**

Jonathan Jarow, MD
Senior Medical Advisor
Office of the Center Director, CDER

Clarifying Questions from the Committee

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

Pyruvic Acid

Brenda Carr, MD
Medical Officer
Division of Dermatology and Dental Products
Office of Drug Evaluation III (ODE III),
OND, CDER

June 23, 2016
Meeting of the Pharmacy Compounding Advisory Committee

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

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

Tea Tree Oil

Hon-Sum Ko, MD
Medical Officer
Division of Dermatology and Dental Products
ODE III, OND, CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Alexander Pytlarz, PharmD
National Community Pharmacist Association
(NCPA)

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

BREAK

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

2,3-Dimercapto-1-propanesulfonic acid (DMPS)

Kathy Robie Suh, MD, PhD
Lead Medical Officer
Division of Hematology Products, OHOP
OND, CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Paul Anderson, ND

Clarifying Questions from the Committee

OPEN PUBLIC HEARING

COMMITTEE DISCUSSION AND VOTE

ADJOURNMENT

Questions to the Committee:

June 23, 2016, a.m. session

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

VOTE: YES, NO, or ABSTAIN for each question

1. FDA is proposing that chrysin NOT be placed on the list of bulk drug substances that can be used in pharmacy compounding in accordance with section 503A of the FD&C Act (“the 503A bulk list”). Should chrysin be placed on the list?

YES: 1 NO: 10 ABSTAIN: 0

Committee Discussion: A majority of the committee agreed that chrysin should not be placed on the list of bulk drug substances. Members voting “NO” commented on the lack of topical and oral bioavailability and effectiveness data. The panel members also commented on the lack of safety data. The committee member who voted “YES” considered the patients that are currently using chrysin and supported continued use, in addition to collecting additional data. Please note that one member who had originally voted “YES” subsequently noted during the explanation of the vote that he meant to vote “NO”. The record was corrected to reflect a “NO” vote. The vote count above records his vote as “NO.” Please see the transcript for details of the committee discussion.

2. FDA is proposing that cesium chloride NOT be placed on the 503A bulk list. Should cesium chloride be placed on the list?

YES: 0 NO: 11 ABSTAIN: 0

Committee Discussion: The committee unanimously agreed that cesium chloride should not be placed on the 503A list of bulk drug substances. Members expressed concerns with the drug’s lack of efficacy, its half-life, strong safety signal, and vulnerability of the population that cesium is intended for. Members commented that cesium chloride should be used in a more controlled environment within the IND process. Please see the transcript for details of the committee discussion.

3. FDA is proposing that sodium dichloroacetate NOT be placed on the 503A bulk list. Should sodium dichloroacetate be placed on the list?

YES: 0 NO: 11 ABSTAIN: 0

Committee Discussion: The committee unanimously agreed that sodium dichloroacetate should not be placed on the 503A bulk list. Members commented on the lack of evidence for efficacy and the high safety risk. They also expressed concerns with the instability of the product. Please see the transcript for details of the committee discussion.

June 23, 2016, p.m. session

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

VOTE: YES, NO, or ABSTAIN for each question

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

YES: 9 NO: 2 ABSTAIN: 0

***Committee Discussion:** The majority of the committee agreed that pyruvic acid should be placed on the 503A bulk list. The members who voted "YES" commented that the safety data presented show no concerns. These members further commented that there is plenty of evidence to support efficacy. Members that voted "NO" expressed concerns with safety because of the vapors of the product and didn't see a compelling need of the product given the currently available FDA approved products. Please see the transcript for details of the committee discussion.*

2. FDA is proposing that tea tree oil NOT be placed on the 503A bulk list. Should tea tree oil be placed on the list?

YES: 8 NO: 2 ABSTAIN: 1

***Committee Discussion:** The majority of the committee agreed that tea tree oil should be placed on the list of 503A bulk drug substances. The members who voted "YES" commented that there is potential utility for tea tree oil for a large percentage of the population with resistance to currently available therapies for dermatophytes. Members also noted that the drug is well characterized with minimal toxicity, but should be limited to topical use. Members of the committee who voted "NO" commented that the efficacy data were not compelling. The one member who voted "ABSTAIN" supports the topical use for tea tree oil, but was uncertain about other routes of administration. Please see the transcript for details of the committee discussion.*

3. FDA is proposing that 2,3-dimercapto-1-propanesulfonic acid (DMPS) NOT be placed on the 503A bulk list. Should DMPS be placed on the list?

YES: 8 NO: 3 ABSTAIN: 0

***Committee Discussion:** The majority of the committee agreed that DMPS should be placed on the 503A list of bulk drug substances. The members who voted "YES" commented*

that the drug should be available when it is necessary despite the misuse potential and emphasized that it should be limited to intravenous administration and hospital use only. Members of the committee who voted "NO" commented that there should be an alternate avenue for access to this drug for legitimate use and preferred to minimize the risk to a large population. Please note one member who had originally voted "NO" subsequently noted 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 5:07 p.m