Waiver to Allow Participation in a Food and Drug Administration Advisory Committee

DATE: August 10, 2018

TO: Rachel Sherman, MD, M.P.H.
Principal Deputy Commissioner
Office of the Commissioner, Food and Drug Administration

THROUGH: Russell Fortney
Director, Advisory Committee Oversight and Management Staff
Office of Special Medical Programs

FROM: Jayne E. Peterson, B.S. Pharm., J.D.
Director, Division of Advisory Committee and Consultant Management
Office of Executive Programs
Center for Drug Evaluation and Research

Name of Advisory Committee Member: **Stephen Hoag, Ph.D.**

Committee: Pharmacy Compounding Advisory Committee (PCAC)

Meeting date: September 12, 2018

Description of the Particular Matter to Which the Waiver Applies:

Dr. Hoag is a standing voting member of the Pharmacy Compounding Advisory Committee. The committee's function is to provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs.

The committee will meet on September 12, 2018, to discuss bulk drug substances nominated for inclusion on the 503A Bulks List. The nominators of these substances will be invited to make a short presentation supporting the nomination. One of the bulk substances to be discussed is pyridoxal 5-phosphate (used for epilepsy and seizure disorder). The topic to be discussed during this meeting is a particular matter involving specific parties.

Type, Nature, and Magnitude of the Financial Interests:

Dr. Hoag owns stock in three companies, (b) (6) that make products that compete with pyridoxal 5-phosphate. The total market value of his stock holdings in these companies is between $100,001 and $300,000.

Under a regulatory exemption issued by the Office of Government Ethics, an employee may participate in any particular matter in which the disqualifying financial interest arises from the ownership of securities issued by one or more entities that are not parties to the matter but that are affected by the matter, if the aggregate market value of the holdings in the securities of all affected entities does not exceed $25,000. Because Dr. Hoag's financial interests in (b) (6) exceed that amount, he has disqualifying financial interests based on the aggregate value of the stocks he owns.

Basis for Granting the Waiver:

The primary issues for discussion at this PCAC meeting will be bulk drug substances nominated for inclusion on the 503A Bulks List. A fruitful discussion of these matters depends upon having strong expertise in the areas of biopharmaceutics and pharmaceutical formulations. It will be critical to have Dr. Hoag's expertise in biopharmaceutics and in the compounding of human drug products, to ensure the success of this advisory committee meeting.

Dr. Hoag has unique qualifications and specialized expertise needed for this particular matter.

Dr. Hoag received his Ph.D. in pharmaceutics from the University of Minnesota-Twin Cities and his bachelor's degree in biochemistry from the University of Wisconsin-Madison. He is the Director of the Good Manufacturing Practices (GMP) Facility and a Professor at the School of Pharmacy, University of Maryland-Baltimore. He is also on the Faculty Committee of the National Institute of Pharmaceutical Technology and Education. His research areas include: (1) sustained release tablet formulation, dissolution testing, mathematical modeling of tablet compaction, design of tablet machine instrumentation, PC-based data acquisition systems, computer-aided manufacture and formulation, testing of nutritional supplements and PAT; (2) use of mass transport theories to mathematically model calcium alginate gel formation and diffusion of bioactive molecules from alginate gels; (3) prenatal vitamin formulations; and (4) thermal analysis of polymers used in film coating.

It is particularly important to include Dr. Hoag in the upcoming PCAC meeting given his unique expertise and significant experience with the topic. Dr. Hoag has unique expertise in biochemistry, biopharmaceutics, and pharmaceutical formulation. His research areas include sustained release tablet formulation, dissolution testing, mathematical modeling, computer-aided manufacture and formulation. In his role as Director of the university's GMP facility, he provides dosage form design and product development guidance to academic clinicians who perform translational research. Dr. Hoag is one of three people with expertise in pharmaceutics who will be attending this meeting. In addition, he is the only one with specific expertise in biopharmaceutics. As an experienced and long-standing member of the PCAC, it will be essential to have his perspective. Additionally, Dr. Hoag has significant experience in evaluating

the nominated bulk substances for the 503A Bulk Drug List.

The particular matters are sensitive.

The meeting topics are considered to be sensitive. These topics are likely to receive Congressional interest and are related to a significant FDA initiative, namely regulation of drug compounding, and development of the 503A Bulks Drug List as described below.

Dr. Hoag's expertise in these particular matters is necessary in the interest of public health.

Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications or abbreviated new drug applications). One of the conditions that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that a bulk drug substance (active pharmaceutical ingredient) used in a compounded drug product must meet one of the following criteria: (1) complies with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if an applicable monograph does not exist, is a component of a drug approved by the Secretary of Health and Human Services (the Secretary); or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary (the ''503A Bulks List'') (see section 503A(b)(1)(A)(i) of the FD&C Act). Dr. Hoag's unique expertise in pharmaceutical formulation work and good manufacturing practices coupled with his experience evaluating nominated bulk substances for the 503A Bulk Drug List and as a long-standing committee member will ensure a fruitful discussion and a broader public health consideration on the compounding of human drug products.

Accordingly, I recommend that you grant a waiver for Dr. Stephen Hoag, a standing voting member of the Pharmacy Compounding Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. § 208(a).

Certification:

✓ The individual may participate, pursuant to 18 U.S.C. 208(b)(3) – The need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved.

Limitations on the Regular Government Employee's or Special Government Employee's Ability to Act:

_____ Non-voting

_____ Other (specify):

_____

_____

_____ Denied – The individual may not participate.

Russell Fortney -S

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DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300191216, cn=Russell Fortney -S
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for Rachel Sherman, MD, MPH
Principal Deputy Commissioner
Office of the Commissioner, Food and Drug Administration

August 23, 2018
Date