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

DATE: February 27, 2018

TO: Rachel Sherman, MD, MPH
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 Meeting Member: **Ruth Parker, M.D.**

Committees: Arthritis Advisory Committee (AAC) and
Drug Safety Risk Management Advisory Committee (DSaRM)

Meeting dates: April 24-25, 2018

Description of the Particular Matter to Which the Waiver Applies:

Dr. Ruth Parker is a temporary voting member of the April 24-25, 2018, joint meeting of the Arthritis Advisory Committee (AAC) and Drug Safety Risk Management (DSaRM) Advisory Committee. The AAC's function is to review and evaluate data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases, and make appropriate recommendations to the Commissioner of Food and Drugs. The DSaRM's function is to review and evaluate information on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice about the safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances.

The committees will meet on April 24-25, 2018, to discuss supplemental new drug application (NDA) 20998 for Celebrex (celecoxib) capsules submitted by Pfizer, Inc., which includes the results from the PRECISION (Prospective Randomized Evaluation of Celecoxib Integrated Safety vs. Ibuprofen Or Naproxen) trial, a cardiovascular outcomes randomized controlled trial

that compared celecoxib to ibuprofen and naproxen. The committees will determine whether the findings of the trial change FDA's current understanding of the safety of these three NSAIDs. In order to interpret some of the PRECISION findings, the committee will also consider the clinical implications of the drug interactions between each of these three NSAIDs and aspirin in patients taking aspirin for secondary prevention of cardiovascular disease. The topics to be discussed during this meeting include both a particular matter involving specific parties and a particular matter of general applicability.

Type, Nature, and Magnitude of the Financial Interest(s):

Dr. Parker reported that her spouse has a financial interest in two healthcare sector mutual funds: (b) (6) and (b) (6) The aggregate market value of her financial interests in these sector funds is between $0 and $100,000.

Under a regulatory exemption issued by the Office of Government Ethics, an employee may participate in any particular matter affecting one or more holdings of a sector mutual fund where the disqualifying financial interest in the matter arises because of ownership of an interest in the fund and the aggregate market value of interests in all funds in which there is a disqualifying financial interest and which concentrate in the same sector does not exceed $50,000. Because Dr. Parker's aggregate financial interests in (b) (6) exceed that amount, she has a disqualifying financial interest.

Basis for Granting the Waiver:

Along with the safety discussions of Celebrex (celecoxib), ibuprofen, naproxen and aspirin, and clinical implications of the drug interactions, a focus of the committee discussion will include prescription and nonprescription drug labeling and how to convey this information to consumers, patients, and health care professionals.

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

Ruth Parker, M.D., is Professor, Division of General Medicine and Professor of Pediatrics at Emory University School of Medicine as well as Professor, Division of Epidemiology, Emory University Rollins School of Public Health. Dr. Parker received her medical degree from the University of North Carolina, Chapel Hill, and received specialty residency training in pediatrics and internal medicine from the University of Rochester School of Medicine. It is critical that FDA have available her unique expertise in over-the-counter (OTC) labeling at the meeting. Dr. Parker's extensive knowledge in this area is demonstrated by her experience chairing and participating in numerous medication labeling committees and workshops, including five-years of membership on FDA's Nonprescription Drugs Advisory Committee (two years as Chairperson). Dr. Parker has authored many peer-reviewed publications in the field of health literacy. Her input regarding the communication of new safety information is vital to and will uniquely enhance the meeting's discussion.

There is limited expertise available and it is difficult to locate similarly qualified individuals without a disqualifying financial interest.

Three OTC labeling experts were invited to participate in this meeting. Of the three, two were unable to attend due to schedule conflicts. This leaves Dr. Parker as the only OTC labeling expert to attend this meeting.

The particular matter is sensitive.

The meeting topic is sensitive and will likely receive significant public and (non-trade) press interest because the medications discussed are commonly used prescription and OTC pain relievers and fever reducers.

Dr. Parker's expertise in this particular matter is necessary in the interest of public health.

It is critical for the Agency, with input from experts, to determine whether the findings of the PRECISION trial changes FDA's current understanding of the safety of these three commonly used NSAIDs, and the clinical and labeling implications of the drug interactions between each of these three NSAIDs and aspirin in patients taking aspirin for secondary prevention of cardiovascular disease.

Accordingly, I recommend that you grant Dr. Ruth Parker, a temporary voting member, a waiver 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 Special Government Employee's Ability to Act:

_____ Non-voting

_____ Other (specify):

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_____

_____ Denied – The individual may not participate.

Russell Fortney -S

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Date: 2018.03.30 12:08:07 -04'00'

for Rachel Sherman, MD, MPH
Principal Deputy Commissioner
Food and Drug Administration

March 30, 2018
Date