DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

November 20, 2013

Michael Carome, M.D.
Sarah Sorscher, J.D., M.P.H.
Public Citizen's Health Research Group
1600 20th St., NW
Washington, DC 20009

Dear Dr. Carome and Ms. Sorscher:

Thank you for your letter dated August 14, 2013, to the Honorable Kathleen Sebelius, Secretary of the Department of Health and Human Services, requesting that she: (1) direct the Food and Drug Administration (FDA or the agency) to seek a permanent injunction against Specialty Compounding, LLC; (2) request that the Inspector General conduct an investigation into FDA's actions with regard to Specialty Compounding; and (3) direct FDA to review its inspections of compounding pharmacies. Secretary Sebelius has referred this matter to FDA.

Because FDA's investigation remains open, we decline to address your request that FDA seek a permanent injunction against Specialty Compounding. However, we direct your attention to publicly available materials regarding the inspection and the recall, available on FDA's website.[1]

You also asked that Secretary Sebelius request that the Office of the Inspector General (OIG) investigate FDA's actions with regard to Specialty Compounding. We have shared your correspondence with the OIG.

Finally, you asked that Secretary Sebelius direct FDA "to review its inspections of compounding pharmacies since the fall of 2012 and initiate further action against all pharmacies with sterility concerns

[1] As you are aware, the Form FDA 483 issued to Specialty Compounding following the March 18 to 22, 2013 inspection is available at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM345935.pdf. The press release issued by Specialty Compounding regarding its recall is available at: http://www.austincompounding.com/recall-information/. FDA's press release regarding the recall conducted by Specialty Compounding is available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm364644.htm. The Form FDA 483 issued to Specialty Compounding following the August 13 to September 13, 2013 inspection is available at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM368579.pdf.

similar to those observed at Specialty Compounding." The Agency is currently evaluating the information obtained during its inspections at compounding pharmacies and will take action where appropriate to protect the public health. FDA is coordinating closely with the state boards of pharmacy in these matters.

Sincerely,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research