DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

February 11, 2014

Michael Carome, M.D.
Elizabeth Barbehenn, Ph.D.
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, D.C. 20009

Dear Drs. Carome and Barbehenn,

Thank you for your letter of February 5, 2014 to Commissioner Hamburg, Dr. Norman Stockbridge, and myself, in which you raise concerns regarding new drug application (NDA) 203202 for droxidopa (NORTHERA), submitted by Chelsea Therapeutics for the proposed indication of treatment of symptomatic neurogenic orthostatic hypotension (NOH).

As you are aware, we cannot discuss the details of a pending marketing application or investigational new drug application (IND) based on several federal statutes and regulations, including the Freedom of Information Act (FOIA) (5 U.S.C. 552), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)), and FDA regulations (21 CFR 20.61(c); 21 CFR 312.130(b); 21 CFR 314.430(c) and (d)(1)). There are limited exceptions to these restrictions on FDA's discussion of a pending application or IND. For example, the Agency may disclose a summary of safety or effectiveness data, if appropriate, at an Advisory Committee meeting (21 CFR 314.430(d)(1)); it may disclose certain information when a sponsor provides a written authorization permitting FDA to disclose non-public information about its pending application or IND, and it may disclose information to the extent the sponsor itself has publicly disclosed the information.

As you know and reference in your letter, information related to this product was discussed at the January 14, 2014 meeting of the Cardiovascular and Renal Drugs Advisory Committee (CRDAC). We appreciate the Public Citizen's Health Research Group testimony presented at that meeting.

We note your comments regarding droxidopa, notably your concern that the sponsor has failed to demonstrate the effectiveness of droxidopa and, therefore, that the risks of the drug might be outweighed by its benefits. We will take this concern into consideration in our evaluation process.

As always, thank you for sharing your perspective with us.

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