CELLTECH

July 30, 2003

Dockets Management Branch
Food and Drug Administration (HFA - 305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Request to Withdraw Citizens Petition 00P-1370/CP1

Dear Sir or Madam:

The purpose of this communication is to confirm in writing the telephone call between Celltech Pharmaceuticals representatives and Mitchell Weitzman on July 21, 2003 in which Celltech communicated its withdrawal of its citizens petition 00P-1370/CP1 and the related stay of action, received and filed by the Dockets Management Branch on June 27, 2000.

As background, this citizens petition requested the FDA change the established name for Zaroxolyn®Tablets from "metolazone tablets, USP" to "metolazone slow-low release tablets". In addition, a stay of action for approval of any abbreviated new drug applications for generic versions of Zaroxolyn®Tablets (metolazone tablets, USP) or Mykrox®Tablets (metolazone tablets, USP) or any new drug applications for other metolazone products was requested until the established name had been changed. This petition was filed due to a concern that the potential existed for medication errors to occur should a generic version of Zaroxolyn®Tablets become approved. As clearly stated in the product labeling, Zaroxolyn®Tablets and Mykrox®Tablets are not therapeutically equivalent and are not interchangeable. The products are currently differentiated in the marketplace through the use of the trade name prescribed by physicians, however if a generic product were approved, the use of the established name metolazone tablets, USP would be utilized, and thus potentially result in the dispensing of the wrong metolazone product to the patient.

Since the time this citizens petition was filed in 2000, the demand for Mykrox®Tablets has declined dramatically. As a result of this decline in demand, and the potential medication errors that could occur should a generic product be approved, Celltech has taken the decision to remove Mykrox®Tablets from the market in the U.S. Removal of this product from the market will negate the need for a change to the established name of Zaroxolyn®Tablets, since no other branded metolazone product will be available for sale in the U.S.

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Celltech intends to perform a product withdrawal of Mykrox®Tablets from our direct accounts, and we will be in communication with the appropriate personnel within CDER regarding this withdrawal.

If you should have any questions regarding the withdrawal of this citizens petition and associated stay of action, please contact the undersigned, Gail Norris, Vice President and General Counsel at (585) 274-5370, or Michele Bartlett, Director Corporate Compliance and Standards at (585) 274-5547.

Sincerely,

Norman D. LaFrance, MD, FACP, FACNP
Senior Vice President, Medical & Regulatory Affairs