DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 006188

Dava Pharmaceuticals, Inc.
Attention: Susan F. Hamet
Vice President, Regulatory Affairs
Parker Plaza
400 Kelby Street, 10th Floor
Fort Lee, New Jersey 07024

Dear Ms. Hamet:

Please refer to your new drug application (NDA) for Propylthiouracil 50 mg Tablets, USP.

On December 8, 2009, we sent you a letter invoking our authority under section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FDCA) to require safety related label changes to the labeling of Propylthiouracil to address the risk of hepatotoxicity with the use of this drug. The decision to require safety labeling changes was based on new safety information about this risk that has been identified since the product was approved. You were directed to submit, within 30 days of the date of that letter, a prior approval supplement proposing changes to the approved labeling, or notify FDA that you do not believe a labeling change is warranted, and submit a statement detailing the reasons why such a change is not warranted.

The 30 days have passed and we have not received any submission from you addressing our letter dated December 8, 2009.

Under the authority of Section 505(o)(4)(E) of the FDCA, we are ordering you to make all of the changes in the labeling listed in our December 8, 2009, letter (Attachment A)**.**

Pursuant to Section 505(o)(4)(E), a supplement containing all of the changes to the labeling that are listed in the December 8, 2009 letter must be received by FDA by **February 5, 2010**, for Propylthiouracil.

Alternatively, by **January 26, 2010**, you may appeal this Order using the Agency's established formal dispute resolution process as described in 21 CFR 10.75 and the Guidance on Formal Dispute Resolution: Appeals Above the Division Level. The appeal should be submitted as correspondence to your NDA referenced above. Identify the submission as **FORMAL DISPUTE RESOLUTION REQUEST** both on the cover letter and on the outside envelope. A copy of the submission should be sent to:

Kim Quaintance
Associate Director for Regulatory Affairs
Food and Drug Administration
Office of New Drugs
Building 22, Room 6300
10903 New Hampshire Avenue
Silver Spring, MD 20993

In addition, to expedite coordination of any such appeal, a copy of the submission should also be sent to:

Mehreen Hai, Ph.D.
Regulatory Project Manager
Food and Drug Administration
Division of Metabolism and Endocrinology Products
Building 22, Room 3391
10903 New Hampshire Avenue
Silver Spring, MD 20993

Refer to the Guidance for Industry, "Formal Dispute Resolution: Appeals Above the Division Level" for further instruction regarding the content and format of your request. Questions regarding the formal dispute resolution process may be directed to Kim Quaintance at (301) 796-0140. Appeals received by the Agency later than **January 26, 2010** will not be entertained.

Failure to respond to this Order within the specified timeframes is a violation of section 505(o)(4) of the FDCA and could subject you to civil monetary penalties under section 303(f)(4) of the FDCA, 21 U.S.C. 333(f)(4) in the amount of up to $250,000 per violation, with additional penalties if the violation continues uncorrected. Further, such a violation would cause your product to be misbranded under section 502(z) of the Act, 21 U.S.C. 352(z), which could subject you to additional enforcement actions, included but not limited to seizure of your product and injunction.

If you have any questions, please call Mehreen Hai, Ph.D., Regulatory Project Manager, at (301) 796-5073.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Attachment A: December 8, 2009, PAS Request Letter