DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-649

Ms. Nancy L. Buc
Ms. Deborah Livornese
Buc & Beardsley
919 Eighteenth Street, N.W.
Washington, D.C. 20006-5503

Dear Ms. Buc and Ms. Livornese:

This letter is an interim response to your complaint and request for correction of information pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, 114 Stat. 2763A-153 (2000), hereinafter referred to as "the Federal Data Quality Act," concerning the Food and Drug Administration's (FDA's) presentations and statements made in connection with the review of new drug application (NDA) 21-649, Genasense (oblimersen), for advanced melanoma.

Your complaint was submitted on behalf of your client, Genta Incorporated, and received by the FDA on May 15, 2007; the amendment to the complaint was received electronically on June 26, 2007. Under FDA's data quality guidelines, which are part of the Department of Health and Human Services' *Guidelines for Ensuring the Quality of Information Disseminated to the Public*, the goal of the FDA is to respond to such requests within 60 days of the receipt of the amendment, either by issuing a decision or by informing you that more time is required to respond to the complaint, explaining why, and providing you with an estimated decision date.

We are preparing a response to your request but will need more time to coordinate Agency review. We anticipate that a response will be forwarded to you by October 22, 2007.

Sincerely,

{See appended electronic signature page}

John K. Jenkins, M.D., F.C.C.P.
Director
Office of New Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

cc: Jane Axelrad
Laurie Lenkel
Sheldon Bradshaw

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

John Jenkins

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