



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-640

ISTA Pharmaceuticals, Inc.
Attention: Marvin J. Garrett
V.P. Regulatory Affairs, Quality & Compliance
15279 Alton Parkway, Suite 100
Irvine, California 92618

Dear Mr. Garrett:

This letter is to inform you that the agency has determined that ISTA Pharmaceuticals' Vitrase (hyaluronidase injection) (NDA 21-640), which was approved by FDA on May 4, 2004, is entitled to five-year new chemical entity exclusivity pursuant to section 505(c)(3)(D) and 505(j)(5)(D) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.108(b). ISTA was informed earlier that it had received three years of new clinical investigation exclusivity. However, after reviewing information and data regarding hyaluronidase drug products, which are protein products that have not been fully characterized, the agency has decided that five year exclusivity is appropriate because we have inadequate information to determine whether any active moiety in Vitrase is the same as any previously approved active moiety.

If a drug product has new chemical entity exclusivity, no applicant may submit a 505(b)(2) application or abbreviated new drug application (ANDA) for a drug product that contains the same active moiety for five years from the date of approval. The bar on submission is only four years when the 505(b)(2) application or ANDA contains a challenge to a patent listed for the drug. New chemical entity exclusivity is a bar to submission of certain 505(b)(2) applications and ANDAs. It is not a prohibition on review and approval of any 505(b)(2) application or ANDA that was submitted to the agency before the approval of the product that was granted five year exclusivity.

The exclusivity information in FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* will be updated to reflect this change.

If you have any questions, call Lori M. Gorski, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Jonca C. Bull, M.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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/s/

Jonca Bull
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