II. Award Information/Funds Available

A. Award Amount

The estimated amount of support in FY10 will be up to $100,000 total costs (direct plus indirect costs), with the possibility of 2 additional years of support for a total (over 3 years) of up to $300,000, subject to the availability of funds.

B. Length of Support

The award will provide 1 year of support, with the possibility of 2 additional years of support, contingent upon satisfactory performance in the achievement of project and program reporting objectives during the preceding year and the availability of Federal fiscal year appropriations.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at http://www.fda.gov. Persons interested in applying for a grant may obtain an application at http://grants.nih.gov/grants/forms.htm. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.) For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With Central Contractor Registration
- Step 3: Register With Electronic Research Administration (eRA) Commons

Steps 1 and 2, in detail, can be found at http://www07.grants.gov/applicants/organization_registration.jsp. Step 3, in detail, can be found at https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp. After you have followed these steps, submit paper applications to: Kimberly Pendleton, Division of Acquisition Support and Grants (HFA–500), Food and Drug Administration, 5630 Fisher Lane, rm. 2104, Rockville, MD 20857, 301–827–9363, FAX: 301–827–7101, e-mail: Kimberly.Pendleton@fda.hhs.gov.


Leslie Kux,
Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–P–0157]

Determination That VESANOID (Tretinoin) Capsules, 10 Milligrams, Were Not Withheld From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that VESANOID (tretinoin) Capsules, 10 milligrams (mg), were not withheld from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of the abbreviated new drug application (ANDA) that refers to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Molly Flannery, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 51, Rm. 6237, Silver Spring, MD 20993–0002, 301–796–3543.