DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Office of Orphan Products Development *(HF-35)*
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Date: April 3, 2006

From: Marlene E. Haffner, M.D., M.P.H.
Director, Office of Orphan Products Development (HF-35)
Office of the Commissioner

Subject: Docket 92S-0251 - Transmittal

To: Chief, Dockets Management Branch, HFA-305

Pursuant to 21 CFR Part 11.2(b)(2), and on behalf of the Office of Orphan Products Development (OPD), please find attached notification of OPD's readiness to accept electronic regulatory submissions for:

Submission: Orphan-Drug Designation Requests
Humanitarian Use Device Designation Requests
Related Submissions – correspondence, annual reports, amendments

Regulatory Citation: 21 CFR 316 and 814.

Effective Date: April 1, 2006

Please add the attached notification to the official docket 92S-0251.

On April 1, 2006, OPD will begin accepting orphan-drug and humanitarian use device designation requests and related submissions in electronic format only through use of physical media (e.g., CD-ROMs) as described in the guidance document Providing Regulatory Submissions in Electronic Format – Orphan-Drug and Humanitarian Use Device Designation Requests and Related Submissions. This guidance is available on the FDA website at the following address: http://www.fda.gov/OHRMS/DOCKETS/98fr/06d-0128-gdl0001.pdf.

Electronic submissions will eventually be made to OPD in one of two ways, totally electronic through the FDA Electronic Submission Gateway (ESG) pathway or directly to OPD through use of physical media (e.g., CD-ROMs). However, the ESG pathway has not been cleared to begin receiving submissions and cannot be utilized at this point in time. Instructions on each procedure and on formatting of submissions are included in the Guidance. Questions regarding electronic submissions to OPD can be made to: desigesub@fda.hhs.gov for orphan-drug designation requests or hudesub@fda.hhs.gov for HUD designation requests.