**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

# Memorandum

Date

From JonnaLynn Capezzuto, Paperwork Reduction Act Analyst
Office of the Chief Information Officer, FDA

Subject Request for OMB Approval for "Orphan Drug Products; Common EMEA/FDA Application Form for Orphan Medicinal Product Designation (Form FDA 3671)" (OMB No. 0910-0167) -- AMENDMENT

To Brenda Aguilar, FDA Desk Officer
Office of Information and Regulatory Affairs, OMB
Through: Reports Clearance Officer, HHS

This memorandum is to request an amendment to OMB Control No. 0910-0167 to add a new form (FDA 3671, "Common EMEA/FDA Application Form for Orphan Medicinal Product Designation") that sponsors may complete to request orphan designation of a drug. This form can be used to submit a designation request to FDA as well as the European Medicines Agency (EMEA). The EMEA information represents an increase in burden of 1,280 hours. Therefore, the total estimate annual burden for 0910-0167 (currently approved burden plus this amendment) is 47,565.

JonnaLynn Capezzuto

Attachments