DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date September 24, 2003

From Mark R. Gregory
Director, Office of Information Technology
ORA, HFC-30

Subject Docket 92S-0251 – Update Transmittal

To Chief, Dockets Management Branch, HFA-305

Pursuant to 21 CFR Part 11.2(b) (2), and on behalf of the Office of Regulatory Affairs, please find the attached notification that ORA is able to access electronic Chemistry Manufacturing and Control submissions thru the Center for Drug Evaluation and Research's Electronic Document Room. This includes both New Drug Applications and Abbreviated New Drug Applications as described in 21 CFR 314.440(a)(4). Sponsors submitting electronic submissions to CDER do not need to submit an electronic submission or paper submission to the ORA District Office. ORA requests that the sponsor submit a letter to their home district certifying that the electronic CMC section has been submitted to CDER.

Submission: New Drug Applications & Abbreviated New Drug Applications
Regulatory Citation: 21CFR 314.440(a)(4)
Effective Date: October 1, 2003

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

For guidance regarding submission of electronic submissions, ORA would defer to CDER and the existing Docket 92S-0251, including Memorandum #6 New Drug Application Submissions and Memorandum #24 Abbreviated New Drug Applications.

Attachment