MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

DATE: November 28, 2001

FROM: Ralph B. Lillie, Director,

Office of Information Technology

CDER, HFD-070

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 Center for Drug Evaluation and Research (CDER) please remove from public Docket 92S-0251 the following item:

Memorandum: 12

Received: May 18, 2001

Submitter: CDER

Record Name: <u>Postmarketing Expedited Safety Reports – 15-Day Alert Reports</u>
Regulatory Citation: 21 CFR 310.305(c), 314.80(c)(1), 314.98 and 600.80(c)(1)

Effective Date: 05/18/01

This item has been superseded by the item announcing Center's readiness to accept Postmarketing Expedited and Periodic Individual Case Safety Reports in Electronic Format forwarded to you 11/28/01, with a suggested effective date of 11/29/01.