MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research

DATE: September 24, 2003

FROM: Linda D. Burek, Director,
Office of Information Technology
CDER, HFD-070

SUBJECT: Docket 92S-025 1 - Electronic Submission of Postmarketing Expedited Periodic Individual Case Safety Reports

TO: Chief, Dockets Management Branch, HFA-305

Pursuant to 2l CFR Part 11.2(b) (2), the attached notifices announces CDER's readiness to accept electronic regulatory submissions for:

Submission: Postmarketing Expedited and Periodic Individual Case Safety Reports including descriptive material.

Regulatory Citation: 21 CFR 310.305(c), 3 14,80(c), 3 W-98, and 600,80(o)

Effective Date: 9/24/2003

Memorandum 23 to docket 92S-0251 (dated 5/22/2002), announced the Center's readiness to accept electronically ICSR information but specifically excluded accompanying descriptive information from electronic submissions.

This notification updates Memorandum 23 by enabling sponsors to electronically submit posmarketing expedited and periodic ICSR records with accompanying descriptive information.

The descriptive information portion of postmarking periodic adverse drug experience reports (21 CFR 3.14.80(c)(2)(ii)(a) and (c) and 600.80(c)(2)(ii)(A) and (C)) may, as of the effective date of this notice, now be submitted to FDA electronically.

Please refer to Memorandum 23 of this docket for additional information.

92S-0251

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