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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-1833]

SoloPak Laboratories, Inc.; Withdrawal of Approval of 1 New Drug Application and 38 Abbreviated New Drug Applications; Correction
AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the FEDERAL REGISTER of June 21, 1999 (64 FR 33097). The document announced the withdrawal of approval of 1 new drug application (NDA) and 38 abbreviated new drug applications (ANDA's) held by SoloPak Laboratories, Inc. The document omitted language explaining that the sponsor voluntarily removed the products from the market because of discrepancies concerning the data submitted to support continued approval of the applications. This document corrects that omission.

EFFECTIVE DATE: (Insert date of publication in the FEDERAL REGISTER.)

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

In FR Doc. 99-15581, appearing on page 33097 in the Federal Register of Monday, June 21, 1999, the following correction is

cd9957

NCR1

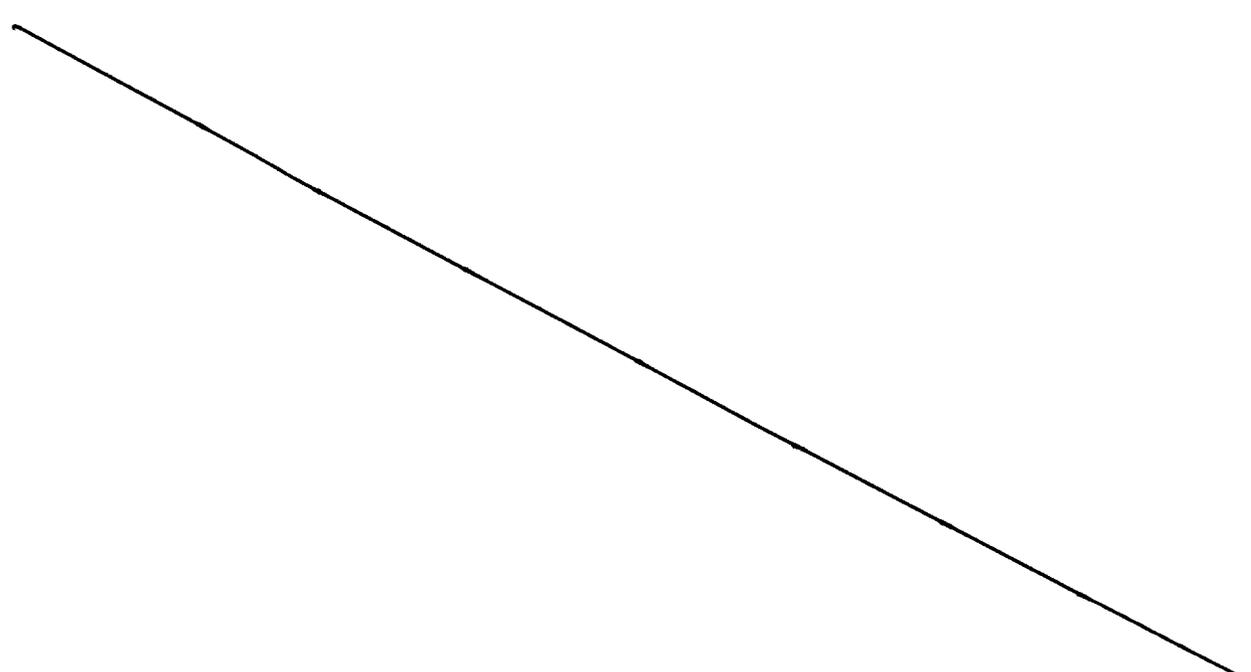
made: On page 33098, immediately preceding the table, add the following two paragraphs to read as follows:

Recently, FDA became aware of discrepancies concerning the data submitted to support continued approval of the following ANDA's held by SoloPak:

ANDA 88-457; Heparin Lock Flush Solution USP, 10 units/milliliter (mL); and

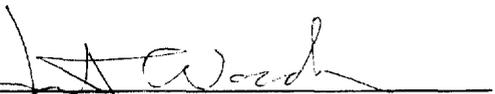
ANDA 88-519; Phenytoin Sodium Injection USP, 50 milligrams (mg)/mL.

After careful review of inspectional findings, the agency determined that there was sufficient justification to initiate proceedings to withdraw approval of the two products listed above. SoloPak was notified in writing of the determinations and, in accordance with § 314.150(d) (21 CFR 314.150(d)), was offered an opportunity to permit FDA to withdraw the applications. Subsequently, in letters dated December 15, 1998,



and March 31, 1999, SoloPak requested withdrawal under
§ 314.150(d) of the applications listed in the following table,
thereby waiving its opportunity for a hearing.

Dated: 7/8/99
July 8, 1999



Janet Woodcock
Director
Center for Drug Evaluation and Research

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

