Certification Regarding Environmental Tobacco Smoke

Public Law 103–227, Part C—Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor routinely owned or leased or contracted for by an entity and used routinely or regularly for provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1000 per day and/or the imposition of an administrative compliance order on the responsible entity.

By signing and submitting this application the applicant/grantee certifies that it will comply with the requirements of the Act. The applicant/grantee further agrees that it will require the language of this certification be included in any subawards which contain provisions for the children's services and that all subgrantees shall certify accordingly.

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BILLING CODE 4184–01–P

Food and Drug Administration

[Docket No. 95N–0182]

KV Pharmaceutical Co.; Proposal To Withdraw Approval of Two Abbreviated New Drug Applications and One Abbreviated Antibiotic Drug Application; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to withdraw approval of two abbreviated new drug applications (ANDA's) and one abbreviated antibiotic application (AADA) held by KV Pharmaceutical Co., 2503 South Hanley Rd., St. Louis, MO 63144 (KV). The grounds for the proposed withdrawals are (1) that the applications contain untrue statements of material fact; and (2) that based upon new information evaluated together with the evidence available when the applications were approved, there is a lack of substantial evidence that the drugs will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

DATES: A hearing request is due on July 26, 1995; data and information in support of the hearing request are due August 25, 1995.

ADDRESSES: A request for a hearing, supporting data, and other comments should be identified with Docket No. 95N–0182 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Harry T. Schiller, Center for Drug Evaluation and Research (HFD–366), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On February 4, 1992, FDA attempted to inspect KV to determine whether or not the firm was following current good manufacturing practice (CGMP) regulations. The firm, however, refused to provide necessary records as required under the Federal Food, Drug, and Cosmetic Act (the act). (See sections 505(k) and 704 of the act (21 U.S.C. 355(k) and 21 U.S.C. 374).) The agency, therefore, obtained inspection warrants and inspected KV between March 11 and April 23, 1992. Despite the inspection warrants, KV failed to provide all of the documents requested. FDA conducted another inspection of KV between July 31 and November 3, 1992.

During the two 1992 inspections, the agency compared documents and data found at the firm with records previously submitted to FDA in support of KV's AADA and ANDA applications. The agency discovered that KV had submitted false and misleading information in the following applications:

1. AADA 62–047, Erythromycin Ethylsuccinate Oral Suspension, 200 and 400 milligrams (mg);

2. ANDA 71–929, Disopyramide Phosphate Extended Release Capsules, 100 mg; and

3. ANDA 86–538, Nitroglycerin Extended Release Capsules, 2.5 mg.

In support of the AADA and the two ANDA's listed above, KV submitted analytical data necessary for approval and continued approval of the applications, including stability data. During its inspections of KV, the agency discovered documents that showed that KV had made untrue statements in some of the stability data it had submitted in supplements and amendments to the applications. The documents also showed that KV had made untrue statements concerning stability data in annual reports submitted to the applications.

In letters dated June 1, 1993, and November 12, 1993, FDA informed KV that the agency intended to downgrade the therapeutic equivalency rating of the products listed above in the agency's publication ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (the ''Orange Book'') and to begin the administrative procedures necessary to withdraw approval of the products. Accordingly, as explained below, the Director of the Center for Drug Evaluation and Research (the Director) is proposing to withdraw approval of the products' applications.

II. Evidence That the Applications Contain Untrue Statements of Material Fact

The first ground for withdrawing the AADA and two ANDA's listed above is that the applications contain untrue statements of material fact (21 U.S.C. 355(e)(5)). This section presents FDA's general comments on untrue statements and materiality, and then sets forth the specific false and misleading information in the three abbreviated applications.

A. Untrue Statements

The untrue statements submitted by KV in its drug applications include both stability test results that are inconsistent with stability test results retained by the firm and selective or incomplete reporting of stability date.

1. Conflicts Between Information Submitted to the Agency and Information Retained by the Firm

The first type of untrue statement submitted in the drug applications listed above consists of data that differ from data and other primary source information discovered at the firm. The agency concludes in such cases that, in the absence of a satisfactory explanation, the discrepant information in the application is untrue.

Information in an AADA or ANDA, including the facts and data covered by this notice, is generally derivative information. Such information is often a restatement, summary, or copy of original data or other underlying information such as that found in laboratory notebooks not specifically included in the application. The agency believes that original or underlying data generally have a higher degree of reliability because they are the primary sources of the information that are usually created contemporaneously with the event the information describes. Restated, summarized, or copied information submitted in the