

PARKE, DAVIS & CO.

Synapoidin Steri-Vial; Notice of With-
drawal of Approval of New Drug
Application

13284

On October 27, 1971, there was published in the FEDERAL REGISTER 36 F.R. 20619) a notice of opportunity for hearing (DESI 5590) in which the Commissioner of Food and Drugs proposed to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the following new drug application on the basis that the drug is not shown to be safe for use and that substantial evidence of effectiveness is lacking.

NDA 5-590, Synapoidin Steri-Vial containing pituitary-chorionic gonadotropins; Parke, Davis & Co., Joseph Campau Avenue at the River, Detroit, Mich. 48232.

Neither Parke, Davis & Co. nor any other interested person have filed a written appearance of election as provided by said notice. The failure to file such an appearance is construed as an election by such persons not to avail themselves of the opportunity for a hearing.

The Commissioner of Food and Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1053, as amended, 21 U.S.C. 355(e)) and under authority delegated to him (21 CFR 2.120), finds that: (1) New evidence of clinical experience, not contained in the new drug application or not available to the Commissioner until after the application was approved, evaluated together with the evidence available to him when the application was approved, reveals that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved. The use of gonadotropins of animal origin entails the risk of eliciting the formation of antibodies to their animal protein content so that allergic reactions may be produced by their use. Other drugs are available which are of benefit and involve less risk; and (2) new information, evaluated together with the evidence available to him when the application was approved, shows there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

Therefore, pursuant to the foregoing findings, approval of the above new drug application, and all amendments and supplements applying thereto, is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (7-8-72).

Dated: June 23, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

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