F.D.A. Seized 25 Million Birth Control Pills in Dispute Over Advertisements

By HAROLD M. SCHMECK Jr. Special to The New York Times

WASHINGTON, Dec. 31 — The largest seizure of a single prescription drug in the history of the Food and Drug Administration took place recently in an action against a concern on a Pearl River, N.Y.

The seizure, on F.D.A. orders the week involved 25 million birth control pills. The confiscation, conducted on Dec. 20 by F.D.A. agents and Federal marshals, had been previously disclosed, but the size of the seizure has not been known.

The pills, seized from Lederle Laboratories, have a retail value of $1.3 million, according to the F.D.A. The product, called Norlesterone, was seized after a dispute between the drug agency and the Lederle concern that had been going on for almost a year.

The F.D.A. ordered the seizure because agency officials had considered some of the advertising for Norlesterone misleading.

Earlier this year, Lederle stopped the advertising to which the F.D.A. had objected and ran corrective advertisements stating the drug's agency's objections.

Later, however, Lederle resumed use of advertisements that are much like those that had raised the original objections, F.D.A. officials said.

In answer to a query concerning the seizure, Dr. Peter H. Rheinstein of the Food and Drug Administration said he believed it to be the fifth time that the agency had taken such action on the ground of misleading advertising. He published in February, 1975, a picture of a woman who was sixty-nine and was the subject of a warning article that mentioned that the woman had been forced to undergo surgery. The woman was one of the patients who had been treated by the norlesterone drug.

Rheinstein said that he believed the earlier versions employed a direct relationship between estrogen dose levels and the risk of stroke. The F.D.A.'s basic objection was that the company was making unwarranted claims for safety because of the low estrogen level. The corrective notice in the May, 1975, issue of the Journal of the American Medical Association showed the picture of the patient under the article. The correction said that the F.D.A.'s position was that the implication was not supported by substantial evidence.

In a statement released after the seizure, Lederle said, "This action comes as a complete surprise to the company."

In March, during negotiations over the advertisements, an officer of the F.D.A.'s Bureau of Drugs, said that the F.D.A. was not aware of any proof that the Norlesterone was free from risk of stroke.

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The Norlesterone tablets contain relatively small doses of the female hormone estrogen. The F.D.A.'s basic objection was that the company was making unwarranted claims for safety because of the low estrogen level. The corrective notice in the May, 1975, issue of the Journal of the American Medical Association showed the picture of the patient under the article. The correction said that the F.D.A.'s position was that the implication was not supported by substantial evidence.

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