21 REMEDIAL ADVERTISING LETTERS ISSUED BETWEEN JANUARY 1967 AND APRIL 1968

Firm	Drug(s)	Date of letter
Ortho	Ortho-Novum	Feb. 1, 1967.
Wallace	Deprol and Miltown	March 1967.
Roche	Librium	Do.
Abbott	Enduron and Enduronyl	Apr. 13, 1967.
Pfizer	Renese, Renese-R, Rondomycin	May 22, 1967.
Geigy	Hygroton and Regroton	June 1967.
Mead Johnson	Oracon and Questran	June 30, 1967.
Flint	Choloxin	July 20, 1967.
Neisler	Diutensen-R	Aug. 11, 1967.
Astra	Cintanest	Aug. 23, 1967.
Squibb	Mysteclin-F	October 1967.
Organon	Cortropin Gel, Cortropin Zinc, Hexadrol, Hexadrol Phosphate	Oct. 27, 1967.
Lakeside	Norpramin	November 1967.
S. E. Massengill	Predsem, Salcort, Salcort-Delta	Nov. 1, 1967.
Upjohn	Medrol	Nov. 15, 1967.
Armour	H. P. Acthar Gel	Nov. 16, 1967.
PDR	H. P. Acthar Gel, Cortropin Gel, Cortropin-Zinc, Hexadrol, Hexadrol Phosphat7, Norpramin, Predsem, Salcort, Salcort-Delta.	Nov. 22, 1967.
Parke-Davis	Pontsel	Jan. 5, 1968.
Syntex	Norguen and Norinyl	Jan. 22, 1968.
G. D. Searle	Ovulen-21	Jan. 26, 1968.
Geigy	Persantine	Feb. 15, 1968.

RARITAN, N.J., *February 1, 1967.*

DEAR DOCTOR: The Food and Drug Administration has asked us to call your attention to the fact that a claim in our recent advertising of Ortho-Novum SQ* may be misleading.

In our introduction of this product to the medical profession we featured the theme, "The Most Effective Sequential", based on a comparison of pregnancy rates published in manufacturers' package inserts. The Food and Drug Administration has pointed out that such a comparison is invalid because there has been neither a direct comparative study of the efficacy of the three sequential oral contraceptives in the same population nor individual studies of the three products in population groups shown to be comparable. We are therefore discontinuing the promotional theme in question.

ORTHO PHARMACEUTICAL CORP.

CRANBURY, N.J.

DEAR DOCTOR: At the request of the Food and Drug Administration, we are calling your attention to one of our recent advertisements captioned, *"The published clinical studies indicate: 3 of 4 non-psychotic depressions respond to 'Deprol'."* The FDA considers that this advertising may have been misleading.

In the advertisement, we listed 21 studies comprising the total published 'Deprol' literature containing data on *non-psychotic* depressions. While the ad does not reflect the fact, data from these studies were *excluded* in whole or in part if—

(*a*) the diagnosis was not entirely clear;

(*b*) the recommended maximum dose of 6 "Deprol" tablets per day was exceeded;

(*c*) other psychotropic drugs or electroshock were part of therapy.

Moderate, marked, excellent, and complete responses were counted as favorable, while mild, fair, slight, and no responses were counted as unfavorable.

Using the above criteria, the final number of patients included was 323 selected from ten of the 21 listed studies. Nine of the ten studies were uncontrolled, and most patients in the ten studies concomitantly received informal or structured psychotherapy. The reported therapeutic results (ranging from 0% in a study with two non-psychotic depressed patients, through 64% in a study with 53 patients, to 90% in two studies with 38 and 41 such patients respectively) also include, to an undetermined degree, placebo responses and spontaneous remissions known to occur in the therapy of neurotic depression.

The factors noted above represent problems that exist in working with any literature and are present in some "Miltown" advertisements carrying the theme

*Trademark.