should be watched closely for the first 30 minutes; epinephrine should be available. Tapering can be started much sooner than when ACTH is given intramuscular or subcutaneously because with continuous intravenous infusion, clinical results are obtained more rapidly. After obtaining a remission by the intravenous route, further therapy, if necessary, is usually given subcutaneously or intramuscularly in the form of H.P. ACTHAR GEL (Repository Corticotropin Injection) which because of its repository properties fewer injections are required. *LABORATORY TESTS OF ADRENAL CORTICAL FUNCTION: (1) The Four Hour or Thorn Test—An eosinophil count is made in the fasting state and immediately thereafter 25 Units of ACTHAR (Corticotropin Injection) are injected intramuscularly. Another eosinophil count is made 4 hours later. Breakfast may be given following the first eosinophil count but lunch should be withheld until after the second. A fall in eosinophils of 50% or more below the pre-injection level indicates a satisfactory adrenal cortical response. (2) The 8 Hour I.V. Test—25 Units of ACTHAR (Corticotropin Injection) in 500 cc. of 5% dextrose are infused over an 8 hour period. Eosinophils are counted at 0 and 8 hours; a fall of 50% or more is indicative of a responsive adrenal.*

PACKAGE FORMS: H.P. ACTHAR GEL (Repository Corticotropin Injection) is supplied in 5 milliliter multiple-dose vials in strengths of 40 and 80 U.S.P. Units (I.U.) per milliliter; 1 milliliter vials containing 40 and 80 U.S.P. Units (I.U.) per milliliter; and 1 milliliter B–D disposable syringes containing 40 U.S.P. Units (I.U.) per milliliter. ACTHAR (Corticotropin Injection) is supplied as a lyophilized powder in vials containing 25 and 40 U.S.P. Units (I.U.) per vial.

PHYSICIANS' DESK REFERENCE,
Oradell, N.J.

DEAR SIR: The Food and Drug Administration has requested that we call your attention to the monographs for the following products in the current (1967) Physicians' Desk Reference:

	Page
HP Acthar Gel	527
Cortrophin Gel	898
Cortrophin-Zinc	898
Hexadrol	899
Hexadrol Phosphate Injection	899
Norpramin	687
Predsem	812
Salcort	812
Salcort-Delta	812

The FDA considers these monographs to be incomplete in presenting the necessary information for the safe and effective use of these drugs and therefore potentially misleading.

To provide you with the necessary information, we enclose revised monographs for insertion in your 1967 PDR at the pages indicated at the top of each sheet.[1] The nature and extent of the additions and other revisions in the enclosed monographs are emphasized by the use of italics.

Sincerely,

ALBERT B. MILLER,
General Manager.

PARKE, DAVIS & CO.,
Detroit, Mich., January 15, 1968.

DEAR DOCTOR: The Food and Drug Administration has asked us to call your attention to our recent Ponstel® (mefenamic acid) journal advertisement and certain promotional mailing and detailing pieces which the Food and Drug Administration regards as misleading.

The introductory campaign featured results from non-blind clinical trials using only a single 500 mg. dose for several types of pain. The Food and Drug Administration points out that Ponstel has also been studied in several double-blind clinical trials in which the drug was compared to aspirin and other non-narcotic analgesics. These trials demonstrated that Ponstel was essentially equal

[1] Retained in committee files.