REPORT ON PROGESTINS

Scope of the Survey

This survey covered seven drugs, each marketed as a single active ingredient product in one to three dosage forms. Dosage forms covered were tablets and injections or injection suspensions. The following drugs were programmed in the study:

1. (a) Progesterone Tablets N.F.[1]
   (b) Progesterone Injection (Aqueous or oil vehicle) N.F.
   (c) Progesterone Injection (Sterile Suspension) N.F.

2. (a) Medroxyprogesterone Acetate Tablets U.S.P.
   (b) Medroxyprogesterone Acetate Injection (Sterile Suspension) U.S.P.

3. Hydroxyprogesterone Caproate Injection (oil vehicle) U.S.P.

4. Dydrogesterone Tablets N.F.

5. Ethisterone Tablets N.F.

6. Norethindrone Tablets N.F.

7. Norethindrone Acetate Tablets N.F.

Of the 20 domestic formulators known to produce these drugs, samples of batches from 16 firms were collected in this survey. Unavailable for sampling was production from E. W. Heun Company, Maizel Laboratories, and Organics Inc. The result from sampling of Parke Davis' Progesterone Injection Suspension, 25.0 mg/ml, is not listed in Table 1 as a defective sample since an apparent syringeability problem interfered with the analysis.[2]

Sampling Information

Samples were collected under FDA's FORDS (Formulator-Oriented Rx Drug Studies) Program from the formulators (manufacturing plant or primary distribution warehouse) or from their branch warehouses or major accounts. No collections were made at locations more than once removed from the manufacturer. Samples were collected from batches released for distribution by the firms' quality control.

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1. Not available for sampling.
2. See Table 1, Footnote c.