DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

The Honorable Thad Cochran
United States Senator
188 East Capitol Street
Suite 614
Jackson, Mississippi 39201

Dear Senator Cochran:

This is in response to your facsimile of June 27, 1995, on behalf of [redacted] regarding reimbursement for her prescription for progesterone based on a National Drug Code (NDC) designation.

Pursuant to Section 510 of the Federal Food, Drug, and Cosmetic Act and implementing regulations (21 CFR Part 207), drug manufacturers are required to register and list their drug products with the Food and Drug Administration. The manufacturer is then assigned a registration number and a labeler code. The labeler code is the first set of digits in the 10 digit NDC number. The second and third set of digits in the NDC code, the product and package number respectively, are assigned by the manufacturer.

A compounded drug, i.e., a drug compounded by a pharmacist on order of a licensed practitioner, is not subject to these regulations and does not receive an NDC number. Such compounding of drugs is considered the practice of pharmacy/medicine.

If we can be of any further assistance, please let us know.

Sincerely,

for Diane C. Thompson

Diane E. Thompson
Associate Commissioner
for Legislative Affairs