

K961222

SECTION A

JUN 26 1996

510(k) Summary

Required by 21 C.F.R. § 807.92

- I. Submitter
- A. Name: Pharmaceutical Innovations, Inc.
- B. Address: 897 Frelinghuysen Avenue
Newark, NJ 07114-2195
- C. Phone and Fax Numbers: (201) 242-2900 Fax No.: (201) 242-0578
- D. Contact Person: Gilbert Buchalter
- II. Date of Preparation of this Summary: March 27, 1996
- III. Trade Name: **EVRON GEL**
- IV. Common Name: Lubricant
- V. Identification of Legally Marketed Device which Equivalence is Claimed:
- ULTRA/PHONIC** Conductivity Gel and related products (NDC#36-1000-00)
- ULTRA/PHONIC SG** Scanning Gel (NDC#36-1001-00)
- GAMMA** Massage and Ultrasound Gel (NDC#36-1150-00)
- VI. Product Description: Clear, water-soluble lubricating gel
- VII. Statement of Intended Use Compared to Legally Marketed Device

Submitter's lubricant is substantially equivalent to, and has the same intended use as, other products in commercial distribution in the United States prior to May 28, 1976. The proposed change to the lubricant consists of expanding the indications for use to specifically include the facilitation of breast self-examination.

VIII. Discussion of Technological Characteristics:

When doing breast self-examination on dry skin, the individual is hampered by friction between her breast and her fingers. When doing this examination in the shower with soapy water, as recommended by the National Cancer Institute and the American Cancer Society, the examination is easier because of the lubrication provided by soapy water. **EVRON GEL** provides this lubrication in a dry setting (e.g. the individual's bedroom). No other claims are made as to the advantage of **EVRON GEL** in this context. It is a skin lubricant comparable to the use and offering the advantage of soapy water.

IX. Safety

The device for which the added claim for breast self-examination is being made is the same as Submitter's pre-amendment and currently marketed devices. These devices have been in commercial distribution for more than twenty five years and are for use in contact with the human body for periods of time longer than required for self-examination. There have been no changes in the composition, materials or method of manufacture of the device. Thus, there are no new questions of safety and no known information to suggest any concern about safety.

X. Effectiveness

The effectiveness of Submitter's lubricant for use to facilitate breast self-examination is due to its ability to reduce friction through its lubricating properties, therefore making it easier to do a breast self-examination.

Although chemically different from soapy water, the basic mechanism by which both provide increased sensitivity is the same, i.e., increased lubrication or slickness to the surface of the skin. This device provides consumers with the convenience of the soapy shower for the dry portion of the exam and is consistent with adequate instructions for use as recommended by the National Cancer Institute, the American Cancer Society, and other breast self-examination procedures.