

STATE OF OKLAHOMA

1st Session of the 43rd Legislature (1991)

HOUSE BILL NO. 1677

BY: HUTCHCROFT

AS INTRODUCED

AN ACT RELATING TO PUBLIC HEALTH AND SAFETY;

RESTRICTING THE SALE, DELIVERY OR GIVING AWAY OF
NEW DRUGS OR DEVICES WITHOUT APPROVAL; PROVIDING
APPROVAL REQUIREMENTS; REQUIRING CERTAIN APPROVAL
INFORMATION FROM THE DEPARTMENT OF HEALTH;
PROVIDING FOR CODIFICATION; AND PROVIDING AN
EFFECTIVE DATE.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified
in the Oklahoma Statutes as Section 2-312.2 of Title 63, unless
there is created a duplication in numbering, reads as follows:

No person shall sell, deliver, or give away any new drug or new
device unless it satisfies either of the following:

1. It is a new drug, and a new drug application has been
approved for it and such approval has not been withdrawn,
terminated, or suspended under Section 505 of the federal act (21
U.S.C., Sec. 355); or it is a new device for which a premarket
approval application has been approved and such approval has not
been withdrawn, terminated, or suspended under Section 515 of the
federal act (21 U.S.C., Sec. 360e); or

2. The Department of Health has approved a new drug or device application setting forth all of the following information:

- a. full reports of investigations which have been made to show whether or not such new drug or device is safe for use or whether such new drug or device is effective in use under the conditions prescribed, recommended, or suggested in the labeling or advertising of the new drug or device,
- b. a full list of the articles used as components of such new drug or device,
- c. a full statement of the composition of such new drug or device,
- d. a full description of the methods used in, and the facilities and controls used for, the manufacturer, processing, and packing of such new drug or in the case of a new device, a full statement of its composition, properties, and construction and the principles of its operation,
- e. such samples of such new drug or device and of the articles used as components of the drug or device as the department may require, and
- f. specimens of the labeling and advertisements proposed to be used for such new drug or device.

SECTION 2. This act shall become effective September 1, 1991.

43-1-5868

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