HB1721

LRB102 13487 CPF 18834 b

102ND GENERAL ASSEMBLY

State of Illinois

2021 and 2022

HB1721

Introduced 2/17/2021, by Rep. Deanne M. Mazzochi

SYNOPSIS AS INTRODUCED:

410 ILCS 620/3.24 new

Amends the Illinois Food, Drug and Cosmetic Act. Requires a manufacturer of a prescription drug that is sold, offered for sale, or distributed in this State, or placed on a formulary to be eligible for payment, co-payment, or reimbursement in this State, to notify the Department of Public Health of specified information concerning active pharmaceutical ingredients.

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A BILL FOR

AN ACT concerning health.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Illinois Food, Drug and Cosmetic Act is amended by adding Section 3.24 as follows:

(410 ILCS 620/3.24 new)

Sec. 3.24. Active pharmaceutical ingredients. A manufacturer of a prescription drug that is sold, offered for sale, or distributed in this State, or placed on a formulary to be eligible for payment, co-payment, or reimbursement in this State, must notify the Department of Public Health of the following:

(1) the country of origin for the active pharmaceutical ingredient, in a searchable form by proprietary name, such as a brand name, if one is associated with the drug product, and ingredient name, such as a generic chemical name; if the country of origin for a manufacturer varies based on dosage or route of administration, each country of origin shall be specified for each such dosage or route of administration;

(2) the Drug Master File number for any angiotensin II receptor blocker and certification that the active ingredient specification contains a nitrosamine

specification of "Not Detected"; and

(3) the Drug Master File number and drug name for any active pharmaceutical ingredient that contains a nitrosamine specification control because the process of manufacture for the active pharmaceutical ingredient makes use of recycled solvents or catalysts.