S T A T E O F N E W Y O R K

604

2009-2010 Regular Sessions

I N A S S E M B L Y

(PREFILED)

January 7, 2009

Introduced by M. of A. CAHILL -- Multi-Sponsored by -- M. of A. ALFANO -- read once and referred to the Committee on Consumer Affairs and Protection

AN ACT to amend the general business law, in relation to preserving the integrity and safety of pharmaceutical drugs

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. The general business law is amended by adding a new section 392-j to read as follows:

S 392-J. FALSE LABELS AND MISREPRESENTATIONS OF PHARMACEUTICAL DRUGS. 1. A PERSON, WHO WITH INTENT TO DEFRAUD:

A. PUTS UPON A PHARMACEUTICAL DRUG, OR UPON A CASK, BOTTLE, STOPPER, VESSEL, CASE, COVER, WRAPPER, PACKAGE, BAND, TICKET, LABEL OR OTHER THING, CONTAINING OR COVERING SUCH PHARMACEUTICAL DRUG, OR WITH WHICH SUCH A PHARMACEUTICAL DRUG IS INTENDED TO BE SOLD, OR IS SOLD, ANY FALSE DESCRIPTION OR OTHER INDICATION OF OR RESPECTING THE TYPE OF PHARMACEUTICAL SUBSTANCE OR COMPOUND, KIND, NUMBER, QUANTITY, WEIGHT OR MEASURE OF SUCH SUBSTANCE, OR ANY PART THEREOF, OR THE PLACE OR COUNTRY WHERE IT WAS MANUFACTURED OR PRODUCED OR THE QUALITY OR GRADE OF ANY SUCH SUBSTANCE, IF THE QUALITY OR GRADE THEREOF IS REQUIRED BY LAW TO BE MARKED, BRANDED OR OTHERWISE INDICATED ON OR WITH SUCH PHARMACEUTICAL DRUG; OR

B. SELLS OR OFFERS FOR SALE A PHARMACEUTICAL DRUG, WHICH TO HIS OR HER KNOWLEDGE IS FALSELY DESCRIBED OR INDICATED UPON ANY SUCH PACKAGE, OR VESSEL CONTAINING THE SAME, OR LABEL THEREUPON, IN ANY OF THE PARTICULARS SPECIFIED; OR

C. DISTRIBUTES, SELLS OR EXPOSES FOR SALE ANY GOODS IN BULK TO WHICH NO NAME OR TRADEMARK SHALL BE ATTACHED, AND ORALLY OR OTHERWISE REPRESENTS THAT SUCH PHARMACEUTICAL DRUGS ARE THE MANUFACTURE OR PRODUCTION OF SOME OTHER THAN THE ACTUAL MANUFACTURER OR PRODUCER; OR

EXPLANATION--Matter in ITALICS (underscored) is new; matter in brackets [ ] is old law to be omitted.

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D. REMOVES OR CONCEALS OR WHO SHALL CAUSE TO BE, WHOLLY OR IN PART, REMOVED OR CONCEALED FROM OR UPON A PHARMACEUTICAL DRUG THE MARK OF ORIGIN; OR WHO SELLS OR CAUSES TO BE SOLD AN ARTICLE OF MERCHANDISE FROM OR UPON WHICH TO HIS OR ITS KNOWLEDGE, OR TO THE KNOWLEDGE OF HIS OR ITS AGENTS, SERVANTS OR EMPLOYEES THERE HAS BEEN IN WHOLE OR IN PART, REMOVED OR CONCEALED THE MARK OF ORIGIN, OR WHO SELLS OR CAUSES TO BE SOLD A PHARMACEUTICAL DRUG FROM THE INSPECTION OF WHICH SUCH KNOWLEDGE COULD HAVE BEEN OBTAINED, SHALL BE GUILTY OF A MISDEMEANOR, PROVIDED THAT IT SHALL NOT BE DEEMED A VIOLATION OF THIS SECTION IF AT THE TIME OF SALE SAID ARTICLE OF MERCHANDISE AND THE IMMEDIATE AND OUTER CONTAINER OR CONTAINERS THEREOF SHALL BE MARKED, STAMPED, TAGGED, BRANDED OR LABELED IN LEGIBLE AND CONSPICUOUS ENGLISH WORDS WITH SAID MARK OF ORIGIN OR THE CONCEALMENT THEREOF SHALL HAVE COMPLETELY CEASED, IN A CASE WHERE THE PUNISHMENT FOR SUCH OFFENSE IS NOT SPECIALLY PROVIDED FOR OTHERWISE BY STATUTE, IS GUILTY OF A MISDEMEANOR.

2. FOR THE PURPOSES OF THIS SECTION, THE FOLLOWING WORDS SHALL HAVE THE FOLLOWING DEFINITIONS:

A. "PERSON" SHALL BE DEEMED TO INCLUDE A FIRM, PARTNERSHIP, ASSOCIATION OR CORPORATION.

B. "SELL" SHALL BE DEEMED TO INCLUDE OFFER TO SELL, EXPOSE FOR SALE, AND POSSESS WITH INTENT TO DISPOSE OF OR TO SELL.

C. "PHARMACEUTICAL DRUG" SHALL BE DEEMED TO INCLUDE A CASK, BOTTLE, STOPPER, VESSEL, CASE, COVER, WRAPPER, PACKAGE, BAND, TICKET, LABEL OR OTHER THING CONTAINING OR COVERING A PHARMACEUTICAL, OR WITH WHICH PHARMACEUTICAL DRUG IS INTENDED TO BE SOLD, OR IS SOLD.

D. "REMOVE" SHALL BE DEEMED TO INCLUDE DEFACE, ALTER AND OBLITERATE.

E. "CONCEAL" SHALL BE DEEMED TO INCLUDE THE ORIGINAL PLACING OF A MARK OF ORIGIN UPON AN ARTICLE OF MERCHANDISE IN ANY MANNER WHATSOEVER, OR THE ARRANGING OR COMBINING OF TWO OR MORE ARTICLES OF MERCHANDISE INTO A SINGLE UNIT WHEREBY THE MARK OF ORIGIN IS REMOVED FROM OPEN VIEW, OR IS RENDERED ILLEGIBLE OR INCONSPICUOUS.

F. THE TERMS "REMOVE" AND "CONCEAL" ARE NOT TO BE DEEMED MUTUALLY EXCLUSIVE.

3. WHENEVER THERE SHALL BE A VIOLATION OF THIS SECTION, AN APPLICATION MAY BE MADE BY THE ATTORNEY GENERAL IN THE NAME OF THE PEOPLE OF THE STATE OF NEW YORK TO A COURT OR JUSTICE HAVING JURISDICTION BY A SPECIAL PROCEEDING TO ISSUE AN INJUNCTION TO ENJOIN AND RESTRAIN THE CONTINUANCE OF SUCH VIOLATIONS; AND IF IT SHALL APPEAR TO THE SATISFACTION OF THE COURT OR JUSTICE THAT THE DEFENDANT HAS, IN FACT, VIOLATED THIS ARTICLE, AN INJUNCTION MAY BE ISSUED BY SUCH COURT OR JUSTICE ENJOINING AND RESTRAINING ANY FURTHER VIOLATION, WITHOUT REQUIRING PROOF THAT ANY PERSON HAS, IN FACT, BEEN INJURED OR DAMAGED THEREBY. IN ANY SUCH PROCEEDING, THE COURT MAY MAKE ALLOWANCES TO THE ATTORNEY GENERAL AS PROVIDED IN PARAGRAPH SIX OF SUBDIVISION (A) OF SECTION EIGHTY-THREE HUNDRED THREE OF THE CIVIL PRACTICE LAW AND RULES, AND DIRECT RESTITUTION. WHENEVER THE COURT SHALL DETERMINE THAT A VIOLATION OF THIS SECTION HAS OCCURRED THE COURT MAY IMPOSE A CIVIL PENALTY OF NOT MORE THAN FIVE HUNDRED DOLLARS FOR EACH VIOLATION. FOR THE PURPOSES OF THIS SECTION EACH GROUP OF IDENTICAL ITEMS SHALL CONSTITUTE A SINGLE VIOLATION. IN CONNECTION WITH ANY SUCH PROPOSED APPLICATION, THE ATTORNEY GENERAL IS AUTHORIZED TO TAKE PROOF AND MAKE A DETERMINATION OF THE RELEVANT FACTS AND TO ISSUE SUBPOENAS IN ACCORDANCE WITH THE CIVIL PRACTICE LAW AND RULES.

4. BEFORE ANY VIOLATION OF THIS SECTION IS SOUGHT TO BE ENJOINED, THE ATTORNEY GENERAL SHALL BE REQUIRED TO GIVE THE PERSON AGAINST WHOM SUCH PROCEEDING IS CONTEMPLATED NOTICE BY CERTIFIED MAIL AND AN OPPORTUNITY

TO SHOW IN WRITING WITHIN FIVE BUSINESS DAYS AFTER RECEIPT OF NOTICE WHY PROCEEDINGS SHOULD NOT BE INSTITUTED AGAINST HIM, UNLESS THE ATTORNEY GENERAL SHALL FIND, IN ANY CASE IN WHICH HE SEEKS PRELIMINARY RELIEF, THAT TO GIVE SUCH NOTICE AND OPPORTUNITY IS NOT IN THE PUBLIC INTEREST.

5. IN ANY SUCH ACTION IT SHALL BE A COMPLETE DEFENSE THAT THE ACTOR PRACTICE IS, OR IF IN INTERSTATE COMMERCE WOULD BE, SUBJECT TO AND COMPLIES WITH THE RULES AND REGULATIONS OF, AND THE STATUTES ADMINISTERED BY, THE FEDERAL FOOD AND DRUG ADMINISTRATION OR ANY OFFICIAL DEPARTMENT, DIVISION, COMMISSION OR AGENCY OF THE UNITED STATES AS SUCH RULES, REGULATIONS OR STATUTES ARE INTERPRETED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION OR SUCH DEPARTMENT, DIVISION, COMMISSION OR AGENCY OR THE FEDERAL COURTS.

S 2. This act shall take effect immediately.