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COUNCIL OF THE DISTRICT OF COLUMBIA

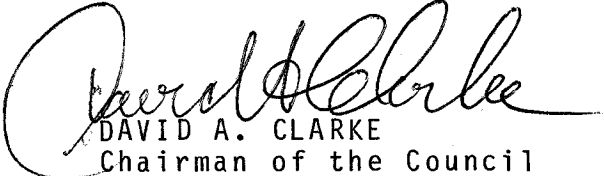
NOTICE

D.C. LAW 8-137

"District of Columbia Drug Manufacture and Distribution Licensure Act of 1990".

Pursuant to Section 412 of the District of Columbia Self-Government and Governmental Reorganization Act, P. L. 93-198, "the Act", the Council of the District of Columbia adopted Bill No. 8-94 on first and second readings, March 13, 1990, and March 27, 1990, respectively. Following the signature of the Mayor on April 17, 1990, this legislation was assigned Act No. 8-193, published in the April 27, 1990, edition of the D.C. Register, (Vol. 37 page 2631) and transmitted to Congress on April 23, 1990 for a 30-day review, in accordance with Section 602(c)(1) of the Act.

The Council of the District of Columbia hereby gives notice that the 30-day Congressional Review Period has expired, and therefore, cites this enactment as D.C. Law 8-137, effective June 13, 1990.


DAVID A. CLARKE
Chairman of the Council

Dates Counted During the 30-day Congressional Review Period:

April 23,24,25,26,27,30

May 1,2,3,4,7,8,9,10,11,14,15,16,17,18,21,22,23,24

June 5,6,7,8,11,12

D.C. LAW 8 - 137

JUN 13 1990

Codification,
District of Columbia Code
New Chapter 10 of Title 33
(1991 Supplement)

AN ACT

D.C. ACT 8 - 193

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

APR 17 1990

To license the distribution, manufacture, or wholesale of drugs.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this act may be cited as the "District of Columbia Drug Manufacture and Distribution Licensure Act of 1990".

Note,
Section
47-2842

Sec. 2. Definitions.

For the purposes of this act, the term:

New, Section
33-1001

(1) "Distribute" means:

- (A) To sell any drug for resale;
- (B) To act as a broker, agent, distributor, jobber, or wholesaler of any drug; or
- (C) To otherwise negotiate a sale for the resale of any drug.

(2) "Drug" means any substance as defined under section 3 of the District of Columbia Pharmacist and Pharmacy Regulation Act of 1980, effective September 16, 1980 (D.C. Law 3-98; D.C. Code, sec. 2-2002).

Note, Section
2-2001

(3) "Manufacture" means:

- (A)(i) To prepare, produce, propogate, compound, convert, process, or package a drug, either directly or indirectly, by extraction from a substance of natural origin, or independently by means of chemical synthesis;
- (ii) Any packaging or repackaging of the substance or drug;
- (iii) Labeling or relabeling of any drug package or container to further distribution from the original place of manufacture to the person who makes final delivery, distribution, or sale to the ultimate consumer or user.

(B) Manufacture does not include the preparation or compounding of a drug by a pharmacist, practitioner, or any other authorized person who prepares or compounds a drug incidental to administering or dispensing a

drug or conducting research, teaching, or chemical analysis on a drug in the course of professional practice.

(4) "Wholesaler" means any person, including but not limited to, a manufacturer, repackager, own label distributor, jobber, broker, agent, pharmacy, private label distributor, distributor warehouse, wholesale drug warehouse, independent wholesale drug trader, chain drug warehouse, retail pharmacy, or pharmacy that sells more than 5% of its drug inventory to a hospital or other pharmacy, which distributes a drug to a person other than a consumer or patient.

(5) "Conditional license" means a license issued pursuant to specific conditions.

Sec. 3. Prohibitions.

No person shall:

New, Section
33-1002

(a) Manufacture, distribute, or wholesale any drug in the District of Columbia ("District") unless the person holds a license or registration as required by this act issued by the Mayor to manufacture, distribute, or wholesale drugs;

(b) Manufacture, distribute, or wholesale in the District, any drug that is adulterated, misbranded, or otherwise unfit for use;

(c) Engage in manufacturing activities under a license issued pursuant to this act unless performed under the personal and immediate supervision of a pharmacist licensed by the District of Columbia or by an individual certified by the Mayor as having scientific or technical training or experience to perform the duties required to ensure that the licensed activity is conducted in a manner that will protect the public health and safety.

(d) Display, cause, permit to be displayed, or possess a cancelled, revoked, suspended, fictitious, or fraudulently altered license to manufacture, distribute, or wholesale drugs;

(e) Lend or transfer a license to manufacture, distribute, or wholesale drugs;

(f) Fail or refuse to surrender to the Mayor a license to manufacture, distribute, or wholesale a drug, if the license has been suspended, revoked, or cancelled, or if the manufacture, distribution, or wholesale activity has terminated;

(g) Permit an unlawful use of a license;

(h) Misrepresent or fail to state a material fact to the Mayor with respect to a license application or a licensee's activities;

(i) Falsely represent to any person that he or she is licensed;

(j) Obtain a drug unless the drug is obtained legally from a legally authorized manufacturer, distributor, or wholesaler; or

(k) Violate any provision of this act, rules issued pursuant to this act, or any applicable federal or District law.

Sec. 4. License requirements.

New, Section
1-1003

(a) To obtain a license to manufacture, distribute, or wholesale any drug, any person who has a principal place of business in the District shall submit a completed application form with the required application fee to the Mayor and comply with the requirements of this act and the rules issued pursuant to this act.

(b) If a person manufactures, distributes, or wholesales any drug at more than 1 place of business in the District, the person shall apply for a separate license for each place of business.

(c) If a licensee manufactures, distributes, or wholesales a drug not listed on the application, the licensee shall notify the Mayor prior to the commencement of the activity.

(d) If a licensee ceases to manufacture, distribute, or wholesale any drug listed in the application, the licensee shall notify the Mayor of the change no later than 7 days after ceasing the activity.

(e) Each licensee shall maintain records as required by the Mayor, including but not limited to the quantities of each drug manufactured, distributed, or wholesaled daily and the name, address, purchaser, place of delivery, and quantity of any drug sold, transferred, or distributed by a licensee.

Sec. 5. Licensure of a drug manufacturer, distributor, or wholesaler.

New, Section
33-1004

The Mayor shall make available a license application form that requests:

(1) The name of the applicant and the address of the place of business for which the applicant seeks a license;

(2) If the applicant is a corporation, the name and address of each officer or director of the corporation and each stockholder who owns 10% or more of any 1 class of stock in the corporation or who owns 10% or more of the total stock of the corporation;

(3) If the applicant is a partnership or joint venture, the name and address of each partner or joint venturer. If a partner or joint venturer is a corporation, any information required pursuant to paragraphs (2) and (9)

of this subsection shall be provided by the partner or joint venturer;

(4) A description of the activity for which the applicant seeks a license;

(5) A list of any drugs that the applicant proposes to manufacture, distribute, or wholesale in the District;

(6) Proof of current approval by the United States Food and Drug Administration for registration of producers of drugs and medical devices pursuant to section 360 of the Federal Food, Drug and Cosmetic Act ("Food, Drug and Cosmetic Act"), approved June 25, 1938 (52 Stat. 1040; 21 U.S.C. 360);

(7) If the applicant proposes to manufacture, distribute, or wholesale a controlled substance as defined section 802 of the Drug Abuse Prevention and Control Act, approved October 27, 1970 (84 Stat. 1242; 21 U.S.C. 802), proof of current registration with the Mayor and the United States Drug Enforcement Administration;

(8) A valid certificate of occupancy; and

(9) A certificate of good standing from the Mayor if the applicant is a corporation.

Sec. 6. Renewal of license.

Prior to the expiration of a license, the Mayor shall mail a renewal notice to the licensee that includes:

(1) The expiration date of the current license;

(2) The date by which the renewal application must be received by the Mayor in order for the renewal license to be issued and mailed to the licensee before the licensee's current license expires;

(3) The amount of the renewal fee; and

(4) Any other information the Mayor deems appropriate or necessary to renew the license.

New, Section
33-1005

Sec. 7. Conditional license.

The Mayor may issue a conditional license to a person, if the person does not meet all of the requirements of this act, the rules issued pursuant to this act, or any applicable federal law, provided the failure to meet the requirements does not endanger the health, safety, or welfare of the community, and the Mayor mandates that the requirements be met by a specific date.

New, Section
33-1006

Sec. 8. Registration of an out-of-state drug manufacturer, distributor, repackager, and wholesaler.

(a) An out-of-state drug manufacturer, distributor, or wholesaler who conducts distribution activities within the District shall register with the Mayor on a form prescribed

New, Section
33-1007

by the Mayor, renew the registration as required by rule, and pay the required registration fee.

(b) A person registered to conduct distribution activities within the District shall be licensed or registered and in good standing under federal law and the laws of the state in which the person is incorporated or has a principal place of business.

(c) The Mayor may withdraw a registration for failure to maintain a license or registration in good standing under state or federal law.

Sec. 9. Inspections.

(a) The Mayor shall conduct an on-site inspection of an applicant's facility before a license is granted.

(b) The Mayor, at any reasonable hour and consistent with constitutional guidelines, may enter a facility to conduct an announced or unannounced inspection of the facility to determine if the facility is in compliance with this act, the rules issued pursuant to this act, or any other District or locally enforceable federal law applicable to the manufacture, distribution, or wholesale of drugs.

New, Section
33-1008

Sec. 10. Summary Action.

(a) If the Mayor determines that the conduct of a licensee presents an imminent danger to the health and safety of the residents of District, the Mayor may suspend or revoke the license, or convert the license to a conditional license of the drug manufacturer, distributor, or wholesaler prior to a hearing.

(b) At the time of the suspension, revocation, or restriction of a license, the Mayor shall provide the licensee with written notice that states the action being taken, the basis for the action, and the right of the licensee to request a hearing.

(c) A licensee shall have the right to request a hearing within 3 days of service of notice of the suspension, revocation, or restriction of the license. The Mayor shall hold a hearing within 3 days of receipt of a timely request and shall issue a decision within 3 days of the hearing.

(d) The Mayor shall inform the licensee of the decision in writing and provide findings of fact and conclusions of law. The findings shall be supported by reliable, probative, and substantial evidence. The Mayor shall provide a copy of the decision to each party to a case or to his or her attorney of record.

(e) Any person aggrieved by a decision pursuant to this section may file an appeal with the Mayor within 10 days of the decision.

New, Section
33-1009

Sec. 11. Suspension, denial, or revocation.

New, Section
33-1010

(a) The Mayor may deny, suspend, or revoke a license, or convert the license to a conditional license, if the Mayor determines that:

(1) The person has violated a provision of this act, the rules issued pursuant to this act, or any other applicable federal or District law; or

(2) The person fraudulently or deceptively obtained or attempted to obtain a license in violation of this act, the rules issued pursuant to this act, or any other applicable federal or District law.

(b) The Mayor shall revoke any license issued pursuant to this act upon conviction of the licensee for a criminal violation of this act, the rules issued pursuant to this act, or any applicable federal law.

Sec. 12. Criminal action.

New, Section
33-1011

A person who willfully violates section 3(a) is guilty of a misdemeanor, and upon conviction, shall be fined not more than \$5,000 for the 1st offense or \$10,000 for the 2nd or subsequent offense, imprisoned for not more than 1 year, or both. Each day that a violation continues is a separate violation under this act.

Sec. 13. Civil infractions.

New, Section
33-1012

Civil fines, penalties, and fees may be imposed as sanctions for any violation of this act or the rules issued pursuant to this act, pursuant to titles I-III of the Department of Consumer and Regulatory Affairs Civil Infractions Act of 1985, effective October 5, 1985 (D.C. Law 6-42; D.C. Code, sec. 6-2701 et seq.).

Sec. 14. Cease and desist order; embargo.

New, Section
33-1013

(a) If the Mayor determines that a hazardous condition exists that may endanger the health, safety, or welfare of the community, the Mayor may issue a cease and desist order to require a violator to cease operation immediately. Any person subject to a cease and desist order may appeal the cease and desist order within 7 days, excluding Saturdays, Sundays, and legal holidays, but shall be required to comply with the order pending appeal. The Mayor shall hold a hearing within 7 days of the receipt of a timely request and issue a decision within 7 days after the hearing.

(b) If the Mayor determines that a drug is adulterated or misbranded, the Mayor may order that the drug be removed from availability for distribution, sale, consumption, or use, or that the drug be destroyed or embargoed.

Sec. 15. Rules.

New, Section
33-1014

(a) The Mayor shall issue rules pursuant to this act in accordance with the provisions of Title I of the District of Columbia Administrative Procedure Act, approved October 21, 1968 (82 Stat. 1204; D.C. Code, sec. 1-1501 et seq.).

(b) The proposed rules shall include, but not be limited to:

- (1) A schedule of license fees;
- (2) Standards for the exemption of certain employees employed by a licensed manufacturer, distributor, or wholesaler;
- (3) Procedures to govern the issuance, denial, renewal, suspension, conversion, or revocation of a license.
- (4) Standards pertaining to labeling, handling, recordkeeping, and storage.


Sec. 16. Exceptions.

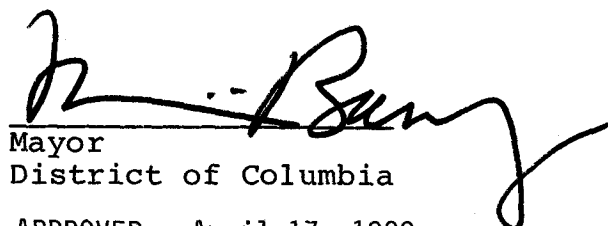
This act shall not apply to any cosmetic unless the cosmetic is a drug as defined by section 321 of the Food, Drug and Cosmetic Act.

New, Section
33-1015

Sec. 17. Effective date.

This act shall take effect after a 30-day period of Congressional review following approval by the Mayor (or in the event of veto by the Mayor, action by the Council of the District of Columbia to override the veto) as provided in section 602(c)(1) of the District of Columbia Self-Government and Governmental Reorganization Act, approved December 24, 1973 (87 Stat. 813; D.C. Code, sec. 1-233(c)(1)), and publication in either the District of Columbia Register, the District of Columbia Statutes-at-Large, or the District of Columbia Municipal Regulations.


Chairman
Council of the District of Columbia


Mayor
District of Columbia

APPROVED: April 17, 1990



COUNCIL OF THE DISTRICT OF COLUMBIA
Council Period Eight

RECORD OF OFFICIAL COUNCIL VOTE

DOCKET NO: Bill 8-94

Item on Consent Calendar

ACTION & DATE: Adopted First Reading, 3-13-90

VOICE VOTE: Approved

Recorded vote on request

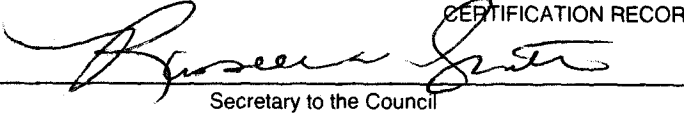
Absent: Mason

ROLL CALL VOTE: -- RESULT _____ (/ /)

COUNCIL MEMBER	AYE	NAY	N.V.	A.B.	COUNCIL MEMBER	AYE	NAY	N.V.	A.B.	COUNCIL MEMBER	AYE	NAY	N.V.	A.B.
CHMN. CLARKE					MASON					THOMAS, SR.				
CRAWFORD					NATHANSON					WILSON				
JARVIS					RAY					WINTER				
KANE					ROLARK									
LIGHTFOOT					SMITH, JR.									

X — Indicates Vote A.B. — Absent N.V. — Present, not voting

CERTIFICATION RECORD


Secretary to the Council

4-4-90
Date

Item on Consent Calendar

ACTION & DATE: Adopted Final Reading, 3-27-90

VOICE VOTE: Approved

Recorded vote on request

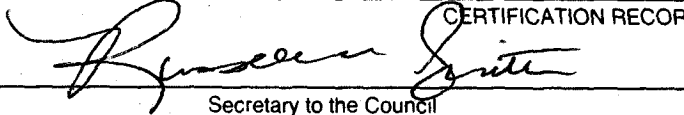
Absent: Thomas

ROLL CALL VOTE: -- RESULT _____ (/ /)

COUNCIL MEMBER	AYE	NAY	N.V.	A.B.	COUNCIL MEMBER	AYE	NAY	N.V.	A.B.	COUNCIL MEMBER	AYE	NAY	N.V.	A.B.
CHMN. CLARKE					MASON					THOMAS, SR.				
CRAWFORD					NATHANSON					WILSON				
JARVIS					RAY					WINTER				
KANE					ROLARK									
LIGHTFOOT					SMITH, JR.									

X — Indicates Vote A.B. — Absent N.V. — Present, not voting

CERTIFICATION RECORD


Secretary to the Council

4-4-90
Date

Item on Consent Calendar

ACTION & DATE: _____

VOICE VOTE: _____

Recorded vote on request

Absent: _____

ROLL CALL VOTE: -- RESULT _____ (/ /)

COUNCIL MEMBER	AYE	NAY	N.V.	A.B.	COUNCIL MEMBER	AYE	NAY	N.V.	A.B.	COUNCIL MEMBER	AYE	NAY	N.V.	A.B.
CHMN. CLARKE					MASON					THOMAS, SR.				
CRAWFORD					NATHANSON					WILSON				
JARVIS					RAY					WINTER				
KANE					ROLARK									
LIGHTFOOT					SMITH, JR.									

X — Indicates Vote A.B. — Absent N.V. — Present, not voting

CERTIFICATION RECORD

Secretary to the Council

Date