

IMPORTANT NOTIFICATION

To all users of the Illinois Department of Public Health Certificate of Free Sale Program

As of November 14, 2014, the governing program code [77 Ill. Adm. Code 720] has been amended and the procedure for obtaining a certificate has changed. Please review the attachments carefully before submitting another request.

All requests received after November 14, 2014, shall follow the new rules and guidelines, and requestors shall utilize the new request form and template.

November 19, 2014

Dear Certificate of Free Sale Requestor:

On November 14, 2014, the Food, Drug and Cosmetic Code [77 Ill Admin. Code 720] was amended. A version of the Code preceded by sections of the associated law is attached to this communication and will soon be available on the Illinois Department of Public Health website.

The following is a summary of important changes that all certificates of free sale requestors should be aware of:

Definitions for the following terms were added to the

Code: Act
Apostille
Certificate of Free Sale
Certificate of Good Manufacturing Practices
Certificate of Origin
Certificate of Sanitation
Difference of Opinion Among Experts
Item
Labeling
Single-service plant

A summary of the changes to the Code by section follows;

A new section, 720.35, contains the requirements for the application and issuance of certificates of free sale.

Special Notice

Attached are the new instructions and request form, effective November 14, 2014. Please review the information and follow the instructions carefully. Incorrect or incomplete requests will be returned. If you have any questions, feel free to contact the program staff by email at dph.freesale@illinois.gov.



Sincerely,

Melissa Estes
Export Program Officer
Division of Food, Drugs and Dairies
Illinois Department of Public Health

PUBLIC HEALTH (410 ILCS 620/) Illinois Food, Drug and Cosmetic Act.

(410 ILCS 620/1) (from Ch. 56 1/2, par. 501)

Sec. 1. This Act shall be known and may be cited as the Illinois Food, Drug and Cosmetic Act. (Source: Laws 1967, p. 959.)

(410 ILCS 620/2) (from Ch. 56 1/2, par. 502)

Sec. 2. In this Act unless the context otherwise requires, the words and phrases defined in Sections 2.1 through 2.39, have the meanings set forth therein. (Source: P.A. 84-891.)

(410 ILCS 620/2.1) (from Ch. 56 1/2, par. 502.1)

Sec. 2.1. "Director" means the Director of Public Health; except that in regard to new animal drugs, animal feed, meat and poultry and meat and poultry food products other than those sold at retail, "Director" means the Director of Agriculture. (Source: P.A. 84-891.)

(410 ILCS 620/2.2) (from Ch. 56 1/2, par. 502.2)

Sec. 2.2. "Person" includes individual, partnership, corporation and association. (Source: Laws 1967, p. 959.)

(410 ILCS 620/2.3) (from Ch. 56 1/2, par. 502.3)

Sec. 2.3. "Food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. (Source: Laws 1967, p. 959.)

(410 ILCS 620/2.4) (from Ch. 56 1/2, par. 502.4)

Sec. 2.4. (a) "Drug" means (1) articles recognized in the official United States Pharmacopoeia - National Formulary, official Homeopathic Pharmacopoeia of the United States, United States Dispensatory, or Remington's Practice of Pharmacy, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2) or (3); but does not include devices or their components, parts or accessories. (b) "Synthetic drug product" means any product that contains a substance defined as a controlled substance under subsections (d) and (e) of Section 204 of the Illinois Controlled Substances Act. Products approved by the U.S. Food and Drug Administration for human consumption are not synthetic drug products. (Source: P.A. 97-872, eff. 7-31-12.)

(410 ILCS 620/2.5) (from Ch. 56 1/2, par. 502.5)

Sec. 2.5. "Device" (except when used in Sections 2.11 and 3.10 and subsection (f) of Section 11, subsections (c) and (p) of Section 15, and subsection (c) of Section 19) means instruments, implements, machines, implants, in vitro reagents, apparatus and contrivances, including their components, parts and accessories, or other similar or related articles which are (1) recognized in the official United States Pharmacopoeia - National Formulary or any supplement thereto; (2) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or other conditions in man or other animals; or (3) intended to affect the structure or any function of the body of man or other animals; and which do not achieve any of their principal intended purposes through chemical action within or on the body of man or other animals and which are not dependent upon being metabolized for the achievement of any of their principal intended purposes. (Source: P.A. 84-891.)

(410 ILCS 620/2.6) (from Ch. 56 1/2, par. 502.6)

Sec. 2.6. "Cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles, except that such term shall not include soap. (Source: Laws 1967, p. 959.)

(410 ILCS 620/2.8) (from Ch. 56 1/2, par. 502.8)

Sec. 2.8. "Label" means a display of written, printed or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper. (Source: Laws 1967, p. 959.)

TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER m: FOOD, DRUGS AND COSMETICS

PART 720
FOOD, DRUG AND COSMETIC CODE

Section	
720.10	General Regulations
720.20	Definitions
720.25	Referenced Materials
720.30	Prohibited Acts and Penalties
720.35	Certificate of Free Sale
720.40	Food
720.50	Drugs and Devices
720.60	Cosmetics

AUTHORITY: Implementing and authorized by the Illinois Food, Drug and Cosmetic Act [410 ILCS 620].

Section 720.10 General Regulations

- a) The provisions of this Part with respect to the commission of any act shall be applicable also to the causing of the act to be done.
- b) The definitions and interpretations of terms contained in Section 2 of the Act shall be applicable also to those terms when used in this Part.

Section 720.20 Definitions

Act – the Illinois Food, Drug and Cosmetic Act.

Apostille – a document that certifies the validity of an Illinois notary public, county clerk, circuit clerk or local registrar.

Certificate of Free Sale – a document issued to Illinois food and dairy manufacturers, processors, packers or warehousemen that are inspected by the Department, verifying that the specified items are freely marketed in the United States and eligible for export to any foreign country as long as that particular manufacturer, processor, packer or warehouseman has no unresolved enforcement actions pending before the Department in accordance with this Part, the Act, the Grade A Pasteurized Milk and Milk Products Act and Grade A Pasteurized Milk and Milk Products administrative rules, the Manufactured Dairy Products Code, and the Manufacturing, Processing, Packing or Holding of Food Code. A Certificate of Free Sale may be issued as an equivalent certificate to include a Certificate of Origin, Certificate of Good Manufacturing Practices, or Certificate of Sanitation.

Certificate of Good Manufacturing Practices – equivalent to a certificate of free sale that certifies that the items were made using good manufacturing practices in an Illinois manufacturing facility.

Certificate of Origin – equivalent to a certificate of free sale to certify that the items were manufactured in Illinois.

Certificate of Sanitation – equivalent to a certificate of free sale to certify that the food items manufactured in Illinois meet applicable food sanitation standards.

Difference of Opinion Among Experts – the existence of a difference of opinion, among experts qualified by scientific training and experience, as to whether the truth of a representation made or suggested in the labeling is a fact (among other facts), the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to the representation.

FDA – United States Food and Drug Administration.

Item – each single unit listed on the Certificate of Free Sale request form.

Labeling – all written, printed or graphic matter accompanying an article at anytime while the article is for sale or delivery, held for sale or offered for sale in Illinois.

Single-service Plant – an Illinois facility that manufactures single-service containers and closures for milk and milk products in accordance with the Grade A Pasteurized Milk and Milk Products Code and FDA Pasteurized Milk Ordinance (PMO) Appendix J.

Section 720.25 Referenced Materials

- a) The following Illinois statutes are referenced in this Part:
 - 1) Illinois Food, Drug and Cosmetic Act [410 ILCS 620]
 - 2) Grade A Pasteurized Milk and Milk Products Act [410 ILCS 635]
- b) The following federal statutes are referenced in this Part: Food, Drug and Cosmetic Act (21 USC 352)
- c) The following Illinois administrative rules are referenced in this Part:
 - 1) Grade A Pasteurized Milk and Milk Products (77 Ill. Adm. Code 775)
 - 2) Manufactured Dairy Products Code (77 Ill. Adm. Code 785)
 - 3) Manufacturing, Processing, Packing or Holding of Food Code (77 Ill. Adm. Code 73)

Section 720.35 Certificate of Free Sale

a) Requirements for Issuance of Certificate of Free Sale

1) The Department will approve issuance of a certificate of free sale only for items that are from Illinois food and dairy manufacturers, processors, packers or warehousemen or an Illinois single-service plant that manufactures single-service containers and closures and is approved for the listing of certified single-service manufacturers in the current publication of the FDA Interstate Milk Shippers (IMS) List.

2) *The Department is authorized, but is not required, upon request, to issue certificates of free sale to Illinois dairy, drug, cosmetic, or medical device manufacturers, processors, packers, or warehousemen (Section 21.3 of the Act).* The Department will not approve a certificate of free sale for medical equipment, devices, drugs, cosmetics, vitamins, and dietary supplements as defined in the Act, even if manufactured, processed, packaged or stored in Illinois.

3) The Department will not issue a certificate of free sale to a business, corporation or entity that is only headquartered in Illinois but manufactures, processes, packs or warehouses in another state.

4) The Department will not modify the language on the certificate of free sale from the original wording.

5) The certificate of free sale covers only existing conditions of the items and shall not be interpreted as a guarantee, explicit or implied, for all items of the company at all times in the future.

6) The issuance of a certificate of free sale does not preclude the Department from taking enforcement action against a food or dairy manufacturer, processor, packer or warehouseman in the future in accordance with this Part, the Act, the Grade A Pasteurized Milk and Milk Products Act, and Grade A Pasteurized Milk and Milk Products administrative rules, the Manufactured Dairy Products Code, and the Manufacturing, Processing, Packing or Holding of Food Code.

b) Application Process for the Certificate of Free Sale

1) The applicant shall complete and submit the Department certificate of free sale request form and payment per the instructions. The request form will be located on the Department website (www.idph.state.il.us).

2) A certificate of free sale will only be made available in English or Spanish. If the applicant needs the certificate of free sale in any other language or dialect, the applicant shall pay the cost of the Department's hiring of a translator to create the requested foreign language certificate of free sale.

- 3) On the application, the applicant shall provide the Illinois State Identification Number or Illinois Permit Number that has been issued to the Illinois manufacturer, processor, packer, distributor or warehouser upon inspection by the Department.
- 4) Along with the application, the applicant shall submit a fee to the Department for the certificate of free sale. A certificate of free sale will include no more than five items. The fee for each certificate of free sale will be \$10.
- 5) Certificates of free sale issued by the Department will be notarized by a certified State of Illinois notary public. If the applicant requires a certificate of authority for the signing notary public or requires an apostille to certify the Illinois notary public, then the applicant shall include a cover letter with its application stating the request and a check payable to the "Secretary of State" in an amount in accordance with the Illinois Secretary of State Notary Services found at <http://www.cyberdriveillinois.com/departments/index/notary/home.html>.

Illinois Department of Public Health **Certificate of Free Sale Program Overview**

The Illinois Department of Public Health (IDPH) shall only approve issuance of a Certificate of Free Sale for items that are from Illinois food and dairy manufacturers, processors, packers, warehouses or Illinois single-service container manufacturers **that are inspected, surveyed, permitted or licensed by the Department.**

Medical equipment, devices, drugs, cosmetics, vitamins, and dietary supplements are not inspected by the Department and therefore, shall not be issued a Certificate of Free Sale from the Department. The Department will not issue a Certificate of Free Sale for items from facilities that are only headquartered in Illinois where there is no manufacturing, processing, packing or warehousing.

The Certificate of Free Sale covers only existing conditions of the items and shall not be interpreted as a guarantee, explicit or implied, for all items of the said company at all times in the future. The issuance of a Certificate of Free Sale does not preclude the Department from taking regulatory action against such items in the future, if action is warranted.

Program preparation guideline requirements

- 1. Submit ONLY one** single page completed request form per request package **regardless of the number of certificates needed.** A form is not required per certificate. This request form shall serve as the cover letter to the Department so DO NOT include an additional letter to IDPH.
- 2. Complete the fillible template.** Upon completion **print in color** 8.5 X 11 landscape document and submit as instructed.
 - a. Prepare the certificate wording using the attached format sample. The wording shown in the sample is the only wording allowed and shall be used. You are allowed to personalize the designated areas only. Full company plant address required, (Number, street and city required)
 - b. Five (5) product maximum listing name only (*NO lot #'s, expiration dates, container or shipment details, etc.*)
 - c. Correct number of certificates printed We do not make copies any longer (If 17 certificates are needed, print 17 for signature)
- 3.** If a Spanish Certificate version is required the Spanish template will be provided upon request. All other language versions shall be available upon request and for an additional charge.
- 4.** Enclose the required \$10 PER CERTIFICATE fee using a check or money order payable to the Illinois Department of Public Health.
- 5.** Enclose a stamped, pre-addressed return envelope or completed express label with your account number for the return of requested certificate(s).

Questions shall be directed to dph.freesale@illinois.gov.
Allow a minimum of 2 weeks for IDPH to process all requests.

When a Certificate of Authority or Apostille is needed, include the requirements for the Secretary of State, Index Department along with your Free Sale request. Provide a forwarding mail method to them so at the completion of our work, we may forward all documents on to them and they will forward all documents back to you. Go to <http://www.cyberdriveillinois.com/departments/index/apostilles.html> for their guidelines.

CERTIFICATE OF FREE SALE REQUEST FORM

Company Name
Company Illinois Address
IDPH Issued ID #
Company Contact
Contact Telephone
Contact E-Mail

Total number of certificates requested _____ X \$10 total amount submit \$ _____

Submission for request shall include all the following:

- 2.** One request form with all blanks properly filled

- 3.** Certificate template(s) (*printed in color*) 8.5 X 11 landscape version
 - a. Full company plant address required, (Number, street and city required)
 - b. Five (5) product maximum listing name only (*NO lot #s or expiration dates allowed*)
 - c. Correct number of certificates printed (If 17 are needed, print 17 to send)
We will make **no** copies

- 4.** Correct Total Fee Amount, (# certificates X \$10)

- 5.** Return mail method, (*self address stamped envelope or filled out airbill with company's account number*)

Mail to: Export Program Officer
Illinois Department of Public Health
Division of Food, Drugs and Dairies
525 W. Jefferson St.
Springfield, IL 62761

Request received:
Certificate mailed: (Department use only)