

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 1) Heading of the Part: The Illinois Food, Drug and Cosmetic Act
- 2) Code Citation: 77 Ill. Adm. Code 720
- 3)

<u>Section Numbers:</u>	<u>Proposed Action:</u>
720.10	Amend
720.20	Amend
720.25	New Section
720.35	New Section
- 4) Statutory Authority: Illinois Food, Drug and Cosmetic Act [410 ILCS 620]
- 5) A Complete Description of the Subjects and Issues Involved: The Department has issued Certificates of Free Sale for all product items (food, drugs, cosmetics) under the Illinois Food, Drug and Cosmetic Act for a \$10 fee to include an unlimited number of items. This rulemaking develops new rules for issuance of Certificates of Free Sale to only Illinois Food and Dairy Manufacturers, Processors, Warehousemen and Packers, or those facilities which the Department inspects, permits or surveys. In addition, the rulemaking states that a certificate of free sale will include no more than five items. Section 720.10 is being added to update the statutory citation and to make other technical corrections. A new Section is being added to list referenced materials.

The economic effect of this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the *Illinois Register*.

- 6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: Other states' rules on issuance of certificates were utilized to develop Illinois' rulemaking on issuance of Certificates of Free Sale.
- 7) Will this rulemaking replace any emergency rulemaking currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this rulemaking contain incorporations by reference? No
- 10) Are there any other proposed rulemakings pending on this Part? No

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- 11) Statement of Statewide Policy Objectives: This rulemaking does not create or expand any State mandates on units of local government.
- 12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking:

Interested persons may present their comments concerning this rulemaking within 45 days after the publication of this issue of the *Illinois Register* to:

Susan Meister
Division of Legal Services
Illinois Department of Public Health
535 W. Jefferson St., 5th floor
Springfield, Illinois 62761

217/782-2043
e-mail: dph.rules@illinois.gov

- 13) Initial Regulatory Flexibility Analysis:
- A) Types of small businesses, small municipalities and not for profit corporations affected: Illinois Food and Dairy Manufacturers, Processors, Packers and Warehousemen
- B) Reporting, bookkeeping or other procedures required for compliance: There will be no change.
- C) Types of professional skills necessary for compliance: None
- 14) Regulatory Agenda on which this rulemaking was summarized: July 2013

The full text of the Proposed Amendments begins on the next page:

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

PART 720

~~THE ILLINOIS FOOD, DRUG AND COSMETIC CODE ACT~~

Section

720.10	General Regulations
720.20	Definitions
<u>725.25</u>	<u>Referenced Materials</u>
720.30	Prohibited Acts and Penalties
<u>720.35</u>	<u>Certificate of Free Sale</u>
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] (Ill. Rev. Stat. 1983, Ch. 56 1/2, pars. 501 et seq.).

SOURCE: Filed October 29, 1968; codified at 8 Ill. Reg. 16339; amended at 38 Ill. Reg. _____, effective _____.

Section 720.10 General Regulations

- a) The provisions of ~~this Part regulations promulgated under the Illinois Food, Drug and Cosmetic Act (the Act)~~ (Ill. Rev. Stat. 1983, ch. 56 1/2, pars. 501 et seq.) with respect to the doing of any act shall be applicable also to the causing of the such act to be done.
- b) The definitions and interpretations of terms contained in Section 2 of the Act shall be applicable also to those such terms when used in this Part regulations promulgated under the Act.

(Source: Amended at 38 Ill. Reg. _____, effective _____)

Section 720.20 Definitions

Act – the Illinois Food, Drug and Cosmetic Act.

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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.

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

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

Single-service plant – an Illinois facility that manufactures single-service

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containers and closures for milk and milk products in accordance with the Grade A Pasteurized Milk and Milk Products Code and United States Food and Drug Administration (FDA) Pasteurized Milk Ordinance (PMO) Appendix J.

a) ~~Labeling Definition:~~

~~Labeling includes all written, printed or graphic matter accompanying an article at any time while such article is for sale, delivery, held for sale or offered for sale in the State of Illinois.~~

b) ~~Difference of Opinion Among Experts:~~

~~The existence of a difference of opinion, among experts qualified by scientific training and experience, as to 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 such representation.~~

(Source: Amended at 38 Ill. Reg. _____, effective _____)

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.

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Adm. Code 73)

(Source: Added at 38 Ill. Reg. _____, effective _____)

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 United States Food and Drug Administration 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 warehousemen 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

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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, then 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 warehouse 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 of 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>.

(Source: Added at 38 Ill. Reg. _____, effective _____)