

**DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BOARD OF HEALTH**

**NOTICE OF INTENTION
TO REPEAL AND REENACT ARTICLE 71
OF THE NEW YORK CITY HEALTH CODE**

NOTICE OF PUBLIC HEARING

In compliance with §1043(b) of the New York City Charter and pursuant to the authority granted to the Board of Health by §558 of said Charter, notice is hereby given of intention to repeal and reenact Article 71 (Food and Drugs) of the New York City Health Code.

NOTICE IS HEREBY GIVEN THAT THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE WILL HOLD A PUBLIC HEARING ON THE PROPOSAL FROM 2:00 P.M. TO 4:00 P.M. ON TUESDAY, OCTOBER 28, 2008 IN THE THIRD FLOOR BOARDROOM (ROOM 330) AT 125 WORTH STREET, NEW YORK, NEW YORK 10013.

PERSONS INTERESTED IN PRE-REGISTERING TO SPEAK SHOULD NOTIFY, IN WRITING, RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK; (212) 788-5010 BY 5:00 P.M. MONDAY OCTOBER 27, 2008. PLEASE INCLUDE A TELEPHONE NUMBER WHERE, IF NECESSARY, YOU MAY BE REACHED DURING NORMAL BUSINESS HOURS. SPEAKERS WILL BE LIMITED TO FIVE (5) MINUTES.

PERSONS WHO REQUEST THAT A SIGN LANGUAGE INTERPRETER OR OTHER FORM OF REASONABLE ACCOMMODATION FOR A DISABILITY BE PROVIDED AT THE HEARING ARE ASKED TO NOTIFY RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013; (212) 788-5010 BY OCTOBER 17, 2008.

REGISTRATION WILL BE ACCEPTED AT THE DOOR UNTIL 4:00 P.M. HOWEVER, PREFERENCE WILL BE GIVEN TO THOSE WHO PRE-REGISTER.

WRITTEN COMMENTS REGARDING THE PROPOSAL ADDRESSED TO THE ATTENTION OF THE BOARD OF HEALTH, MUST BE SUBMITTED TO RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH BY MAIL TO 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013, BY FAX TO (212) 788-4315, BY E-MAIL TO: RESOLUTIONCOMMENTS@HEALTH.NYC.GOV OR ONLINE (WITHOUT ATTACHMENTS) TO: <http://www.nyc.gov/html/doh/html/notice/notice.shtml> ON OR BEFORE 5:00 P.M., TUESDAY, OCTOBER 28, 2008. ATTACHMENTS TO ONLINE COMMENTS MUST BE MAILED OR FAXED.

WRITTEN COMMENTS RECEIVED BY THE SECRETARY TO THE BOARD OF HEALTH AND A TRANSCRIPT OF THE PUBLIC HEARING WILL BE AVAILABLE FOR PUBLIC INSPECTION WITHIN A REASONABLE TIME AFTER RECEIPT, BETWEEN THE HOURS OF 9:00 A.M. AND 5:00 P.M. AT THE OFFICE OF THE SECRETARY. THE DEPARTMENT'S GENERAL POLICY IS TO MAKE WRITTEN COMMENTS AVAILABLE FOR PUBLIC VIEWING ON THE INTERNET. ALL COMMENTS RECEIVED, INCLUDING ANY PERSONAL INFORMATION PROVIDED, WILL BE POSTED WITHOUT CHANGE TO <http://www.nyc.gov/html/doh/html/comment/comment.shtml>

STATUTORY AUTHORITY

These amendments to the New York City Health Code (“Health Code”) are promulgated pursuant to §§556, 558 and 1043 of the New York City Charter (the “Charter”). Section 556 of the Charter provides the Department of Health and Mental Hygiene (“DOHMH” or “Department”) with jurisdiction to regulate all matters affecting the health in the City of New York. Section 558(b) and (c) of the Charter empower the Board of Health (the “Board”) to amend the Health Code and to include in the Health Code all matters to which the DOHMH’s authority extends. Section 1043 of the Charter grants the DOHMH rulemaking powers.

STATEMENT OF BASIS AND PURPOSE

INTRODUCTION

As part of a comprehensive review of the Health Code to assess the efficacy of its articles in protecting the public’s health, the DOHMH proposes that the Board of Health repeal and reenact Article 71, "Food and Drugs," to better reflect practice and the regulatory environment by, for example, explicitly extending the scope and coverage of the Article to cosmetics; assuring that the revised provisions provide adequate legal tools to effectively address the health and safety needs of the public; and by harmonizing such provisions with related provisions of the Federal Food, Drug and Cosmetic Act, the New York Agriculture and Markets Law and the New York Education Law and regulations promulgated thereunder. As part of the revision effort, particular effort has also been focused on clarifying the enforcement authority of the Department. The proposed changes will better enable the Department to take actions to protect the public from contaminated cosmetic products such as *litargirio*, a lead-containing deodorant powder; mercury-containing skin lightening creams; and herbal medicine products containing hazardous levels of heavy metals. Review and assessment of Article 71 has resulted in amendments to all but one of the sections in the Article, and the DOHMH accordingly proposes that the Board repeal and reenact Article 71 as set forth herein.

§71.01. Scope.

This section would now include cosmetics within the regulatory scope of the Article, which currently applies only to food and drugs. However, the existing regulatory scheme of this Article is intended to be consistent with the regulatory scope of the Federal Food, Drug and Cosmetic Act (the "Act"), which regulates cosmetics. Because adulterated or misbranded cosmetics may have serious or detrimental health and safety effects, the DOHMH has concluded that incorporating the regulation of cosmetics into this Article will enhance the protection of public health. Violations of this Article with respect to cosmetics will result from issues involving product ingredients, contaminants, processing, packaging, labeling, shipping or handling, that cause a cosmetic to be considered adulterated or misbranded.

§71.03. Definitions.

This section would be amended to add, as subdivision (c), a definition of the term “cosmetic,” based on the definition in the Act. The definition of “drug” would be amended to make clear that an article that is intended to be consumed, aspirated or otherwise absorbed, rubbed, poured, sprinkled, sprayed on, introduced or otherwise applied to the human body or any part thereof, will be considered a drug if it is an article that is intended to affect the structure or

any function of the body. This clarification is intended to provide additional guidance on what will be deemed a drug.

§71.05. Adulteration or misbranding prohibited; possession deemed for purpose of sale.

This section would be similar to existing §71.05 and would now include the addition of cosmetics.

Subdivision (c) would conform and update standards for determining whether a food is adulterated in accordance with Federal and State law, clarifying that a food will be deemed adulterated if it bears or contains any added poisonous or added deleterious substance that is unsafe within the meaning of the Act (21 U.S.C. §346), unless such added substance is a pesticide chemical *residue* in or on a raw agricultural commodity, or as determined by the Commissioner. The existing provision refers only to a pesticide chemical. The change to pesticide chemical residue conforms these standards to those of the Federal Act and State law.

Subdivision (d) ("Foods deemed misbranded") would be new and would provide a comprehensive list of criteria for determining when foods are misbranded, consistent with the Federal Act and State law.

Subdivision (e) ("Drug deemed adulterated") would include additional examples of when a drug will be deemed adulterated, derived from the Act and the New York Education Law. Paragraph (9), although not derived from Federal or State law, would be added to provide further protections.

Subdivision (f) ("Drug deemed misbranded") is new and tracks the provisions of the Federal Act.

New subdivisions (g) ("Cosmetic deemed adulterated") and (h) ("Cosmetic deemed misbranded") would reflect the addition of cosmetics to the Article's regulatory scope, would prohibit distribution of cosmetics which are adulterated or misbranded, and would establish standards by which the DOHMH will determine a cosmetic to be adulterated or misbranded, based on the Federal Act and State Education Law.

§71.06. Labeling requirements.

This new section would provide that any required statements and information on the labels for food, drug and cosmetic products must appear in the English language in addition to any information or statements appearing in a foreign language to enable consumers to avail themselves of words, statements or other information required to be provided under applicable law.

§71.09 Records; access and confidentiality.

Existing §71.09 would be updated and clarified regarding redisclosure of pharmacy records.

§71.11. Embargo or seizure.

This section would remain unchanged from existing §71.11, except to add cosmetics to items that may be seized or embargoed.

The Proposal is as follows:

Matter underlined is new

RESOLVED, that Article 71 ("Food and Drugs") and the list of section headings of Article 71 of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be and the same hereby are repealed and reenacted, to be printed together with explanatory notes to read as follows:

Article 71

Food, Drugs and Cosmetics

§71.01 Scope.

§71.03 Definitions.

§71.05 Adulteration or misbranding prohibited; possession deemed for purpose of sale.

§71.06 Labeling requirements.

§71.07 Drugs dispensed on prescription.

§71.09 Records; access and confidentiality.

§71.11 Embargo or seizure.

Introductory Notes:

Article 71 was repealed and reenacted on [] as part of a comprehensive review of the Health Code to assess the efficacy of the articles in protecting the public's health, to better reflect current practice and the regulatory environment by, for example, explicitly extending the regulatory scope and coverage of the Article to cosmetics; assuring that the revised provisions provide adequate legal tools to effectively address the health and safety needs of the public; and by harmonizing such provisions with related provisions of the Federal Food, Drug and Cosmetic Act, and the New York Agriculture and Markets Law and Education Law and related regulations promulgated thereunder.

According to the Food and Drug Administration ("FDA"), the difference between a cosmetic and a drug is determined by a product's intended use. A violation can occur by marketing a cosmetic with a drug claim or by marketing a drug as if it were a cosmetic without adhering to applicable drug requirements promulgated by the FDA. The Federal Food, Drug and Cosmetic Act defines cosmetics by their intended use, and includes in its definition skin creams, lotions, perfumes, lipsticks, fingernail polishes, eye and facial make-up preparations, shampoos,

permanent waves, hair colors, toothpastes, deodorants, as well as any other material intended for use as a component of a cosmetic product. Some products are defined as both cosmetics and drugs when they have two intended uses. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair and an antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug and therefore must comply with the requirements for both cosmetics and drugs.

This Article also clarifies the Department's authority to prohibit the sale and distribution of adulterated and misbranded food, drugs and cosmetics within the City if harmful to the public health. Neither the Federal Food Drug and Cosmetic Act nor the New York State Agriculture and Markets Law or the New York State Education Law contains a definition of "adulteration". Instead, these laws and this Article provide parameters for when regulated foods, drugs and cosmetics will be deemed adulterated.

§71.01 Scope.

Unless otherwise indicated, the provisions of this article apply to all food, drugs and cosmetics.

§71.03 Definitions. When used in this Code:

(a) Food means any raw, cooked or processed edible substances, beverages, ingredients, chewing gum, ice, or water used or intended for use or for sale in whole or in part for human consumption.

(b) Drug means:

(1) An article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them.

(2) An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or condition, or to control a bodily function in humans or animals.

(3) An article other than food that is intended to affect the structure or any function of the body of human or animals, whether intended to be consumed, aspirated or otherwise absorbed, rubbed, poured, sprinkled, sprayed on, ingested, introduced into or otherwise applied to the human body or any part thereof.

(4) An article intended for use as a component of any articles specified in paragraphs (1), (2) or (3) of this subdivision, but does not include a device, instrument, apparatus, or contrivance or their components, parts and accessories, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals; or to affect the structure or any function of the body of humans or animals.

(c) *Cosmetic* means any article 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, including but not limited to personal hygiene products such as deodorant, shampoo or conditioner, and any article intended for use as a component of any such articles.

(d) *Raw agricultural commodity* means any food in its raw or natural state, including all fruits or vegetables, that are washed, colored or otherwise treated in their unpeeled natural form prior to marketing.

(e) *Federal Food, Drug, and Cosmetic Act* means the Federal Food, Drug, and Cosmetic Act of the United States, 21 U.S.C. §301, et seq., as such law may from time to time be amended.

§71.05 Adulteration or misbranding prohibited; possession deemed for purpose of sale.

(a) No person shall manufacture, produce, pack, possess, sell, offer for sale, deliver or give away any food, drug or cosmetic which is adulterated or misbranded. A food, drug or cosmetic in the possession of, held, kept or offered for sale by any person shall, prima facie, be presumed to be held, kept or offered for sale for human consumption or use.

(b) No person shall adulterate or misbrand a food, drug or cosmetic.

(c) *Food deemed adulterated.* A food shall be deemed adulterated if the Department has determined the food to be adulterated or as set forth in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §342) or the New York State Agriculture and Markets Law (§200) under circumstances including, but not limited to, any one or more of the following:

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health.

(2) If it bears or contains any added poisonous or added deleterious substance that is unsafe within the meaning of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §346), or as determined by the Department, unless such added substance is a pesticide chemical residue in or on a raw agricultural commodity, or if it is a processed food, a food additive, or a color additive.

(3) If it is a raw agricultural commodity and bears or contains a pesticide chemical residue, it will be considered adulterated if it is unsafe within the meaning in the Federal Food, Drug and Cosmetic Act (21 U.S.C. §346a).

(4) If the food is, bears or contains any food additive, it will be considered adulterated if it is unsafe within the meaning of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §348).

(5) If it consists in whole or in part of any diseased, contaminated, filthy, putrid or decomposed substance, or if it is otherwise unfit for consumption as food.

(6) If it has been produced, prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.

(7) If it is in whole or in part the product of a diseased animal or of an animal which has died otherwise than by slaughter, or which has fed upon uncooked offal.

(8) If its container is composed in whole or in part of any poisonous or deleterious substance that may render the contents injurious to health.

(9) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. §348) or the New York State Agriculture and Markets Law (§§199-a or 199-b).

(d) *Food deemed misbranded.* A food shall be deemed misbranded in accordance with the Federal Food, Drug and Cosmetic Act (21 U.S.C. §343) or the New York State Agriculture and Markets Law (§ 201) under circumstances including, but not limited to, any of the following:

(1) If its labeling is false or misleading in any particular.

(2) If it is offered for sale under the name of another article.

(3) If it is an imitation of another food, unless its label bears the word "imitation" and immediately thereafter the name of the food imitated in type of uniform size and equal prominence, followed by a statement showing the constituents thereof.

(4) If its container is so made, formed, colored or filled as to be misleading.

(5) If in package form, unless it bears a label containing the name and place of business of the manufacturer, packer, or distributor.

(6) If any word, statement or other information required by or under authority of this Code to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(7) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed, unless it conforms to such definition and standard, and its label bears the name of the food specified in the definition and standard, and, in so far as may be required, the common names of optional ingredients present in such food.

(8) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Commissioner determines to be and prescribes as necessary in order to inform purchasers fully as to its value for such uses.

(9) If a food is not a raw agricultural commodity and it is or it contains an ingredient that bears or contains a major food allergen, unless labeled pursuant to the standards as set forth in the Federal Food, Drug, and Cosmetic Act.

(10) If it is in package form and contains two or more discrete components and does not bear a label containing the contents.

(11) If it purports or is represented to be for special dietary uses, the label of which does not bear such information concerning its vitamin, mineral and other dietary properties as is necessary in order to inform purchasers fully as to its value for such uses.

(12) If it is otherwise mislabeled in a manner that obscures or fails to declare its source, contents, or purpose.

(13) If it is in a package that does not bear a label containing the name and place of business of the manufacturer, packer or distributor.

(e) *Drug deemed adulterated.* A drug shall be deemed to be adulterated if the Department has determined the drug to be adulterated or as set forth in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §351) or the New York State Education Law (§6815) under circumstances including but not limited to, any of the following:

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to users when used in the dosage, or manner or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof or under such conditions of use as are customary or usual.

(2) If it bears or contains any added poisonous or added deleterious substance.

(3) If it consists in whole or in part of any filthy, putrid or decomposed substance.

(4) If it has been prepared, packed or held under unsanitary conditions whereby it may have been contaminated with filth, or rendered injurious to health.

(5) If it is a drug and its container is composed, in whole or in part of any poisonous or deleterious substance that may render the contents injurious to health.

(6) If it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified pursuant to Article 137 of the New York Education Law or the regulations promulgated thereunder.

(7) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. No drug defined in an official compendium shall be deemed to be adulterated under this subdivision because it differs from the standard of strength, quality or purity set forth in such compendium if such difference is plainly stated on the label. When a drug

is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(8) If it is not subject to the provisions of paragraph (5) of this subdivision and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(9) If it is a drug and any substance has been mixed or packed therewith so as to reduce its quality or strength or substituted wholly or in part therefore.

(10) If it is sold under or by a name not recognized in or according to a formula not given in the United States pharmacopoeia or the national formulary but that is found in some other standard work on pharmacology recognized by the board, and it differs in strength, quality or purity from the strength, quality or purity required, or the formula prescribed in, the standard work.

(f) *Drug deemed misbranded.* A drug shall be deemed misbranded as set forth in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §352) or the State Education Law (§6815) under circumstances including, but not limited to, any of the following:

(1) If its labeling is false or misleading in any particular.

(2) If in package form, unless it bears a label containing the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

(3) If any word, statement, or other information required by or under authority of this article to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) *Cosmetic deemed adulterated.* A cosmetic shall be deemed adulterated if the Department has determined the cosmetic to be adulterated or as set forth in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §361) or State Education Law (§6818) under circumstances including, but not limited to, any of the following:

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual, except that this provision shall not apply to any cosmetic product, whose label bears a statement pursuant to 21 U.S.C. §740.1 warning of the hazards associated with use of the product.

(2) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(3) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(4) If its container is composed, in whole or in part, of any poisonous or deleterious substance, which may render the contents injurious to health.

(h) *Cosmetic deemed misbranded.* A cosmetic shall be deemed misbranded as set forth in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §362) or the New York State Education Law (§6818) under circumstances including, but not limited to, any of the following:

(1) If its labeling is false or misleading in any particular.

(2) If in package form, unless it bears a label containing the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the or numerical count, reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations.

(3) If any word, statement, or other information required by or under authority of this article to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(4) If its container is so made, formed, or filled as to be misleading or if it bears a copy, counterfeit, or colorable imitation of a trademark, label, or identifying name or design of another cosmetic.

§71.06 Labeling requirements.

(a) All words, statements, and other information required by applicable law to appear on the label or labeling of food, drug and cosmetic products shall be printed in the English language.

(b) If a label contains any representation in a foreign language, all words, statements, and other information required by or under authority of all applicable laws and regulations to appear on the label shall appear thereon in the foreign language in addition to all information required in the English language.

§71.07 Drugs dispensed on prescription.

(a) A pharmacist shall maintain a file of prescriptions filled and make such file available for inspection by the Department in any matter under investigation by the Department.

(b) Prescriptions shall be retained by the pharmacist for a period of at least five years after such prescriptions are filled by such pharmacist.

§71.09 Records; access and confidentiality.

(a) All records relating to the receipt, holding or movement of foods, drugs or cosmetics required to be maintained pursuant to applicable laws and regulations shall be available for inspection by the Department.

(b) Prescriptions and other reports and records obtained by the Department containing information that identifies a patient or prescriber shall not be subject to inspection by persons other than authorized employees of the Department, and no information obtained by the Department from such prescriptions, reports and records shall be disclosed except for the purpose of protecting the public health.

(c) All records, reports, and files, papers and letters containing information about or relating to adverse reactions, side-effects or therapeutic misuse of any food, drug or cosmetic held, sold, kept for sale or used in the City of New York or which may indicate that any such food, drug or cosmetic may be injurious to or have an adverse effect on the health of persons using the food, drug or cosmetic shall be available for inspection by the Department whenever the Department deems such inspection reasonable and necessary. Any information in the custody or possession of the Department relating to such information shall not be subject to subpoena or inspection by persons other than the Commissioner or authorized employees or agents of the Department, and shall not be divulged by the Department. The Department may, however, disclose or publish summaries, findings or statistical compilations relating thereto.

(d) No person shall refuse to permit an authorized representative of the Department to inspect or copy any record referred to in subdivisions (a), (b) and (c) of this section.

§71.11 Embargo or seizure.

When in the opinion of the Department a food, drug or cosmetic is unfit for consumption or use, or is adulterated or otherwise constitutes a danger or is prejudicial to the public health, the Department may seize, embargo, or condemn such material pursuant to §3.03 of this Code.