DEPARTMENT OF HEALTH AND MENTAL HYGIENE

BOARD OF HEALTH

NOTICE OF ADOPTION OF A RESOLUTION
TO REPEAL AND REENACT ARTICLE 115
AND TO REPEAL OF ARTICLE 116
OF THE NEW YORK CITY HEALTH CODE

In compliance with §1043(b) of the New York City Charter (the "Charter") and pursuant to the authority granted to the Board of Health by §558 of said Charter, a Notice of Intention of the proposed repeal and reenactment of Article 115 and the repeal of Article 116 of the New York City Health Code (the "Health Code") was published in the City Record on March 9, 2007, and a public hearing was held on April 18, 2007. One person testified and five written comments were received. In response to several of the comments, further changes were made to Article 115. At a meeting on October 24, 2007, the Board of Health adopted the following proposal.

STATUTORY AUTHORITY

These amendments to the Health Code are promulgated pursuant to §§558 and 1043 of the Charter. Sections 558(b) and (c) of the Charter empower the Board of Health to amend the Health Code and to include in the Health Code all matters to which the Department's authority extends. Section 1043 grants the Department rule-making authority.

STATEMENT OF BASIS AND PURPOSE

The Commissioner received a petition from a permittee, Infant Formula Laboratory Services, Inc., to commence rule making under Article 9 of the New York City Health Code (Health Code) to amend Article 115 ("Formula Milk for Infants") of the Health Code. Richard Miller, President of the Infant Formula Laboratory Services, Inc., to amend Article 115 to allow for an exception in §115.27 ("Operations; sterilization of formula milk") that would allow a physician to ask that a specific formula be prepared under aseptic conditions and not be sterilized after preparation.

In response to the petition, the Department proposes that Article 115 be repealed and reenacted, to update all of its provisions, not just those pertaining to sterilization of prepared infant formula. As reenacted, Article 115 reflects and is consistent with current practices, and applies to other child and adult formula preparations.

In addition, the Board of Health is repealing in its entirety Article 116 ("Infant Formula in Hermetically Sealed Containers") as its provisions are outdated, and because production of infant food formula, including nutritional standards, labeling requirements and good manufacturing practices, are comprehensively regulated by the Federal Food and Drug Administration (FDA).

Background

There is only one formula preparation facility in the New York Metropolitan area. The Infant Formula Lab Service is a private family owned and operated business which prepares customized infant, toddler, child, and adult nutritional formulas and delivers the prepared formulas to medical facilities. These formulas are prepared from commercially manufactured formula preparations, that are modified,

reconstituted and/or re-formulated upon the order of a physician or other authorized practitioners to meet individual nutrition needs of newborn, pediatric and adult hospitalized patients. Many hospitals, including those operated by the City's Health and Hospital Corporation, use the services of Infant Formula Lab Service because they no longer operate formula rooms in their own facilities. As an infant formula permittee in New York City, Infant Formula Lab Service is required to comply with Articles 115 and 81 ("Food Preparation and Food Establishment"), and other provisions of the Health Code, and under current rules must sterilize all infant milk products prepared. However, the manufacturers of some formulas, whether powdered or liquid, or made with milk or other protein-based food products may specify on their labels that no further sterilization or heat treatment be used following preparation, as sterilization reportedly destroys nutrients. The American Dietetic Association in its *Guidelines for Preparation of Formula and Breastmilk in Health Care Facilities* endorses the use of sterile water, hand antisepsis techniques, sanitization of equipment and utensils, and aseptic (clean or no–touch) technique. Thermal heating is not recommended as a routine method for preparation of infant formula.

The most recent 2004 guidelines of the American Dietetic Association (ADA) for institutional infant feeding preparation do not recommend terminal heating in all cases:

> Terminal heating (pasteurization) is not recommended as a routine method for preparation of formulas for infants in health care facilities, because of potential alteration of the nutritive and physical characteristic of the prepared formula. Terminal heating is a method of heat processing formula used to kill vegetative forms of microorganisms where the formula is heated to a temperature of 180 degrees Fahrenheit (82 degrees Celsius) and then is rapidly cooled to a safe temperature. Most facilities are not able to pasteurize milk. Some formulas for infants, such as those containing free amino acids or small peptides, will be nutritionally compromised by terminal heating. Unless oxygen is eliminated from the head space of the bottles, the degradation of Vitamin C will slowly continue, even though the formula is refrigerated. Other potential problems include changes in the physical elegance of the product and other nutrient degradation with extreme and prolonged heating (greater than 212 degrees Fahrenheit).…Some health care facilities have used autoclaves (steam under pressure) for terminal heating of infant formulas. This method frequently exposed the product to excessive heat, which may result in the carmelization of sugars, physical changes, chemical changes and nutrient loss. Manufacturers of formulas for infants recommend that autoclaves not be used to prepare formula in health care facilities. Autoclaves may be appropriately used only to sanitize empty bottles or equipment[1].

Article 115 is derived from §174 of the City Sanitary Code and Regulations. The original Sanitary Code provision was adopted in 1947, and revised without substantive change in 1959 when it was included in the first publication of the Health Code. It has been amended only twice since then, in 1971 and 2005. Article 115 is now substantially outdated, fails to recognize that infant formula is prepared with other than milk-based food products, and is not applicable, for example, to the following non-milk based preparations.

- Soy-based formulas, suitable for infants who cannot tolerate lactose in most milk-based formulas or who are allergic to the whole protein in cow milk and milk-based formulas. The soy protein is a specific protein isolate fortified with L-methionine, combinations of corn maltodextrin, sucrose, or corn syrup solids provide carbohydrate; and vegetable blends to provide fat. These formulas are marketed in powdered, liquid concentrate, and liquid ready-to-eat forms.

[1] Infant Feedings: Guidelines for Preparation of Formula and Breastmilk in Health Care Facilities, copyright 2004 American Dietetic Association p39.

- Protein hydrolysate-based formulas, for infants with milk allergy or intolerance to intact protein. These formulas are marketed in powdered, liquid concentrate, and liquid ready-to-eat feed forms. Enzymatically hydrolyzed casein, fortified with selected amino acids, provides nitrogen; combinations of corn syrup solids, maltodextrin, or sucrose provide carbohydrate; and vegetable oil blends provide fat. One protein hydrolysate-based product also includes medium chain triglyceride (MCT) oils as a fat source.

- Amino acid-based formula, for infants who do not tolerate formulas based on cow milk proteins, soy protein isolate, or casein hydolysate. At least one amino acid-based formula currently marketed in the United States contains corn syrup solids, free amino acids, and a vegetable oil blend as sources of macronutrients. This amino acid-based formula is available only in powdered form, and loses nutrients if sterilized after being reconstituted.

New Provisions of Article 115

In addition to substituting the term "prescription formula" for the term "formula milk" throughout the article, Article 115 includes the following changes. Changes made in response to public comments are included.

The title has been changed from "Formula Milk for Infants" to "Prescription Formula Preparation Facilities" to reflect the new scope and applicability of the article. The listing of section headings has been amended accordingly to reflect the changes in the section headings of the article.

§115.01 Scope. Reflects the change in applicability from formula milk for infants to all kinds of prescription formulas; indicates that facilities regulated by the article are considered "non-retail food processing establishments" and thereby subject to all applicable provisions of Article 81 of the Code.

§115.03 Definition. The new definition of prescription formula includes not only milk-based formulas but other protein-based formula products such as soy protein–based formulas, protein hydrolysate-based formulas, and amino acid-based formulas. It includes powdered or liquid foods with a basic ingredient of milk, milk constituent, or other liquid or powdered protein–based food which is prepared for an individual infant, child, or adult in accordance with a prescription by a physician or other health care practitioner.

§115.05 Permit. This section has been changed to eliminate permission to operate before a permit has been issued.

§115.07 Compliance with Code. This section has been changed to eliminate reference to specific articles of the Code, and to require compliance with all applicable provisions of the Code.

§115.09 Preparation and sale on physician's or other health care practitioner's order. The original proposal reflected the fact that many orders for modifications of manufactured formula are transmitted by hospital dietitians, eliminating preparing formula in response to requests from nurses, or parents. In response to a comment from two State chapters of the American Academy of Pediatrics, however, that dietitians in hospitals may not lawfully prescribe therapeutic diets, this provision has been further amended to reflect current State law. 10 NYCRR §405.23(c)(1), e.g., provides that "therapeutic diets in a hospital shall be prescribed by the practitioner or practitioners responsible for the care of the patients." In a note to this section, the Department has listed practitioners who are authorized by law to prescribe medications for patients.

§115.11 Standards; ingredients. This section has been amended to eliminate references to milk produced pursuant to Article 111 ("Milk and Milk Products") of the Code. Except for milk dating, Article 111 is also considerably out of date and milk production standards are established and enforced by federal and state authorities.

§115.13 Standards; sterilization and purity of prescription formula preparations. This section has been amended to eliminate the requirement that all prescription formula preparations be sterilized, but continues to require that production facilities and equipment be maintained in sanitary, aseptic conditions, and that samples be periodically analyzed for microbiological contamination pursuant to a schedule approved by the Department. Products which fail such analysis are to be embargoed in accordance with applicable provisions of the Health Code.

§115.15 Time of delivery. Previously titled "Standards; time" this section originally required, instead of delivery on the day of the order, delivery of prepared prescription formula to the person ordering the formula within 24 hours of preparation, to preserve the safety and nutritional quality of the formula. However, in response to comments received referencing the World Health Organization's 2007 guidelines for "Safe preparation, storage and handling of powdered formula," this provision has been further amended to clarify that prescription infant formula preparations that are either prepared from a powder base, or a liquid base that has been amended, be timely delivered so that they may be consumed or destroyed within 24 hours of preparation. Other formula preparations may be consumed or discarded no later than within 48 hours of preparation.

§115.17 Labeling of containers. Previously titled "Standards; labeling" this section now requires labeling of the individual containers of prescription formula, rather than the cartons in which the containers are delivered, and requires labels to include information recommended by the ADA and U.S. Centers for Disease Control and Prevention. Reconstituted powdered infant formula, and liquid infant formula that has been amended must be labeled with a 24 hour use by or discard time, and if made from powder base, be clearly marked as reconstituted from "powdered" formula. To further clarify the labeling requirement in response to a comment, the Code will allow more than one label to be attached to the container if necessary, so that not all information needs to be included on a single label.

§115.19 Physical facilities, equipment and processing deletes provisions that are duplicative of those in Article 81 relating to sanitary conditions required for a non-retail food processing establishment, but retains those that are unique to a facility required to maintain aseptic conditions and to separate preparation and utility functions. A prescription formula preparation facility, as a non-retail food processing establishment, is required to have all food preparation activities supervised by a holder of an approved food protection certificate, in accordance with §81.15 of this Code. Separate rooms are to be used for the preparation adult and children's formula. Preparation rooms must be organized to prevent unsanitary contamination of product and equipment, and to avoid possible allergic reactions and other adverse health effects that may be caused by cross-contamination from different kinds of formula bases.

§115.21 Packaging and sterilization. Lowers holding temperatures of prepared prescription formulas from the current 41° F to 40° F in accordance with ADA Guidelines for Preparation of Formula and Breast Milk in Health Care Facilities for control growth of *E. sakazakii* in manufactured powered infant formula. In response to a comment, attaching a 2007 version of the World Health Organization's guidelines for "Safe preparation, storage and handling of powdered infant," a new subdivision (d) has been added to require that sterile water used in preparation of infant powder based formula be cooled to a temperature no lower than 158° F (70°C) since such a practice was found to dramatically reduce the risk of bacterial infection. As initially published, subdivision (e) [relettered as subdivision (f)] of §115.21 requires that reconstituted powdered formula be cooled to 37° F (2°C to 4°C) within one hour of preparation. Relettered subdivision (f) of §115.21 is derived from ADA Guidelines for Preparation of

Formula and Breast Milk in Health Care Facilities and the Food and Agriculture Organization of the United Nations and the World Health Organization's report on Enterobacter sakazakii and Other Microorganisms in Powdered Infant Formula recommended temperatures for cooling and maintaining reconstituted powdered infant formula to prevent infection with certain microorganisms, including, but not limited to, *E. sakazakii*. Prepared prescription formula must be packaged in individual single service food grade containers, and closed with a cover or cap that effectively seals and protects the mouth of the container. Containers may be closed with suitable, incised nipples protected with fitted outer caps. Containers of prescription formula shall be sterilized unless other processing is required by the physician or practitioner's order, or the manufacturer's label on the package for a specific formula.

§115.23 Records. This provision retains certain record keeping requirements of current §115.29 that are relevant to modern operations of the prescription formula preparation facility, but eliminates those that are no longer applicable.

Finally, Article 116 ("Infant Formula in Hermetically Sealed Containers") should be repealed in its entirety since the FDA now regulates manufacturing of all such formulas. See, 21 CFR Parts 106, 107.

References:

Infant Feedings: Guidelines for Preparation of Formula and Breastmilk in Health Care Facilities, Sandra T. Robbins and Leila T. Beker, editors; Pediatrics Nutrition Practice Group, American Dietetic Association, copyright 2004.

International Food Safety Authorities Network, INFOSAN *Information Note No. 1/2005-Enterobacter sakazakii, Enterobacter sakazakii in powdered infant milk formula*

Enterobacter sakazakii and Other Microorganisms in Powdered Infant Formula, Meeting Report 2004 FAO/WHO Microbiological Risk Assessment Series.

US Centers for Disease Control and Prevention, *MMWR*, April 12, 2002/51(14); 298-300: Enterobacter sakazakii Infections Associated with the Use of Powdered Infant Formula----Tennessee, 2001.

Safe preparation, storage and handling of powdered infant formula; guidelines, 2007, World Health Organization in collaboration with Food and Agriculture of the United Nations.

Statement Pursuant to Charter § 1043

This proposal was not included in the Department's regulatory agenda because it is the result of a petition to amend the Health Code submitted in accordance with Article 9 of the Health Code, received after publication of the regulatory agenda.

The amendment is as follows:

Matter underlined is new

Matter to be deleted is indicated by [brackets].

RESOLVED, that Article 115 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, adopted by resolution in October, nineteen hundred fifty-nine, be, and the same hereby is, repealed and reenacted, to printed together with explanatory notes, to read as follows:

Article 115
Prescription Formula Preparation Facilities

Introductory Notes: Article 115 was repealed and reenacted by resolution adopted on October 24, 2007 to modernize its provisions and eliminate requirements that are no longer applicable.

§115.01 Scope. This Article applies to the individual preparation of formula in accordance with a physician's or other health care practitioner's prescription in a non-retail food processing establishment, as defined in Article 81 of this Code. It shall not apply to preparation of such formula in (1) a maternity and newborn service operating pursuant to Article 28 of the Public Health Law, (2) any other institution giving care to children, or (3) a dwelling unit for the use of a person residing within the unit.

§115.03 Definition. When used in this Article, "prescription formula" means a food that is prepared for an individual, in accordance with the prescription of a physician or other health care practitioner, using a commercially manufactured powder or liquid food with a basic ingredient of milk, milk constituent, soy, or other liquid or powdered protein. This definition shall not limit the ingredients which may be added to any formula prepared pursuant to this Article.

§115.05 Permit. No person shall prepare prescription formula for sale or distribution or offer for sale, sell, give away or distribute prescription formula in or from a prescription formula preparation facility without a permit issued by the Commissioner.

§115.07 Compliance with Code. A prescription formula preparation facility shall be operated, constructed and maintained in the manner specified for non-retail food processing establishments by Article 81 and for buildings generally pursuant to applicable provisions of this Code.

§115.09 Preparation and sale on physician's or other health care practitioner's order. No prescription formula preparation facility permittee shall prepare, offer for sale, sell, give away or distribute prescription formula except on the order of a physician or other health care practitioner authorized by State law to prescribe therapeutic diets. The order may be transmitted to the permittee orally or in writing.

Note: 10 NYCRR §405.23 (c)(1) provides that in a hospital, "therapeutic diets shall be prescribed by the practitioner or practitioners responsible for the care of the patients." Practitioners that are authorized by the State Education Law to prescribe medications include licensed physicians, registered physician's assistants; registered specialist's assistants; certified nurse practitioners and licensed midwives.

§115.11 Standards; ingredients. Food products used in the preparation of prescription formula shall be wholesome and obtained from sources approved in accordance with applicable federal and state law.

§115.13 Standards; sterilization and purity of prescription formula preparations.

(a)Prescription formula preparations shall be safe for human consumption and produced under sanitary conditions using aseptic technique.

(b) Samples of prepared prescription formula shall be submitted to a certified laboratory for bacteriological and other microbiological analysis in accordance with a schedule established by the permittee and approved by the Department.

(c)When bacteriological sampling or other investigation reveals that the prescription formula preparation fails to meet the requirements of this Code, the Department may embargo and exclude such prescription formula from sale or distribution in accordance with Articles 3 and 71 of this Code.

§115.15 Time of delivery. Prescription formula preparations for infants made from a powder base or from a liquid base which have been amended shall be timely delivered to persons ordering such prescription formula so that such preparations may be consumed or discarded within 24 hours of preparation. All other formula preparations shall be consumed or discarded within 48 hours of preparation.

§115.17 Labeling of containers. Each container of prepared prescription formula for an individual shall be labeled with the following information:

(a) The name and telephone number of the prescription formula preparation facility;

(b) The words "INFANT FORMULA"; "CHILD FORMULA" OR "ADULT FORMULA" as applicable, or other words acceptable to the Department;

(c) The patient's name, medical record number or other institutional identification, and name of medical facility;

(d) If the prescription formula is prepared using commercially available infant formula, the infant formula brand name and additives, if any;

(e) Caloric density/volume;

(f) Expiration date and time;

(g) A statement that the prescription formula shall be kept under refrigeration at or below 40 degrees Fahrenheit (4.4 degrees Celsius), except that prescription formula for infants prepared with a powdered food base shall be maintained at temperatures below 37 degrees Fahrenheit (2.8 degrees Celsius);

(h) Prescription formulas for infants made from a powdered food base or a liquid base that has been modified shall be labeled to identify powder content, and shall include a statement that such prescription formulas shall be consumed or discarded no later than 24 hours after preparation. Other formula preparations shall include statement that such prescription formulas shall be discarded no later than 48 hours after preparation.

§115.19 Physical facilities, equipment and processing.

(a) Rooms and equipment used to prepare prescription formula shall be organized, cleaned and sanitized so as to prevent contamination, including cross-contamination by food substances, such as allergens, that the ordering physician or other health care practitioner has indicated may compromise an patient's health and safety.

(b) Facilities shall consist of separate rooms for preparation of infant and adult prescription formula and a separate room or rooms for washing and sanitizing containers and utensils. Such rooms shall not be used for any other purpose.

(c) During prescription formula preparation no other activities shall take place in the preparation room, doors leading to prescription formula preparation rooms shall be kept securely closed during preparation and only authorized personnel shall be allowed access to the prescription formula preparation room(s).

(d) Rooms shall be of such size as to prevent contamination of equipment and utensils.

(e) A preparation room shall have no exposed overhead water, steam or sewage piping and shall have an adequate number of conveniently located hand wash sinks operated by foot, knee or elbow controls.

(f) Floor drains of a washing room shall be separate from the drains of preparation rooms. A washing room shall have facilities and equipment and a supply of hot and cold running water adequate to enable proper cleaning and sterilization of containers and utensils. Racks shall be provided for the storing of clean containers and utensils.

(g) Equipment and apparatus used for preparation of prescription formula shall be of sanitary design and construction and allow effective cleaning and sanitizing. Equipment and apparatus shall be made of

stainless steel or other impervious materials which will not rust, corrode or result in contamination. Sterilization equipment shall be equipped with recording and indicating thermometers.

§115.21 Packaging and sterilization.

(a) Prescription formula shall be packaged in individual single service food grade containers.

(b)Immediately after filling, a container shall be closed with a cover or cap which effectively seals and protects the mouth of the container. Containers with prepared infant prescription formula may be closed with new, unused, incised nipples which shall be protected with suitable outside fitted caps.

(c) Only sterile water shall be used in infant prescription formula preparation.

(d) Sterile water used to prepare infant prescription formula from a powder base shall be cooled to a temperature no lower than 158 degrees Fahrenheit (70 degrees Celsius) during preparation.

(e) Containers of prescription formula shall be sterilized in an autoclave unless the physician or other health care practitioner's order states that such formula shall not be sterilized, or if the label on a container of a commercially manufactured infant formula base advises that such formula should not be sterilized after preparation.

(f) Prepared infant prescription formula shall be properly cooled to and maintained at 40 degrees Fahrenheit (4.4 degrees Celsius) within one hour of preparation, except that prescription infant formula prepared from a powdered food base shall be cooled to 37 degrees Fahrenheit (2.8 degrees Celsius) within one hour of preparation, and maintained at 37 degrees Fahrenheit (2.8 degrees Celsius).

(g) Formula intended for persons other than infants shall be cooled to and maintained at temperatures recommended by the manufacturer of the formula base product, or Article 81, whichever temperature is lower.

(h) All prescription infant formula prepared from a powder base, or liquid containing amendments, shall be used or discarded within 24 hours of preparation. All other formula preparations shall be consumed or discarded within 48 hours of preparation.

§115.23 Records. The following records, in a form provided or approved by the Department, shall be retained for at least three months:

(a) Orders received and prescription formulas prepared in accordance with such orders.

(b) For each sterilization procedure, equipment calibration readings, processing time and temperatures maintained during sterilization.

(c) Reports of bacteriological or other microbiological laboratory analyses conducted by or on behalf of the permittee.

Notes: Article 115, formerly titled "Formula Milk for Infants," was repealed and reenacted by resolution adopted on October 24, 2007 to modernize its provisions, clarify its scope, and extend its applicability to formulas prepared for infants and others, and to formula products based on foods other than milk.

RESOLVED, that Article 116 ("Infant Formula in Hermetically Sealed Containers") of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, as last amended by resolution adopted on the second of July, nineteen hundred sixty-four, be and the same hereby is, repealed.

RESOLVED, that the table of Article headings of Title IV ("Environmental Sanitation") of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, adopted by resolution in October, nineteen hundred fifty-nine, be, and the same hereby is, amended, to be printed together with explanatory notes, to read as follows:

TITLE IV

ENVIRONMENTAL SANITATION

Part A Food and Drugs

Part B Control of Environment

Article 71 Food and Drugs

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113 Frozen Desserts

115 [Formula Milk for Infants] <u>Prescription Formula Preparation Facilities</u>

116 [Infant Formula in Hermetically Sealed Containers] <u>Repealed</u>

117 Dairy Food Products

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Notes: Article 115 ("Formula Milk for Infants") was repealed and reenacted by resolution adopted on October 24, 2007, to modernize its provisions, clarify its scope and extend its applicability to formula preparations for infants and other persons and to formula products based on foods other than milk. Article 116 ("Infant Formula in Hermetically Sealed Containers") was repealed at the same time because its provisions have largely become outdated and because production of infant formula, including nutritional standards, labeling requirements and good manufacturing practices are comprehensively regulated by the Federal Food and Drug Administration.