ARTICLE 115

PRESCRIPTION FORMULA PREPARATION FACILITIES

§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.

§115.0 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.

§115.0 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.

§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);
(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 or below 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 or below 40 degrees Fahrenheit (4.4 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.