the water vapor pressure of the sub-
stance divided by the vapor pressure of
pure water at the same temperature.
We means the U.S. Food and Drug
Administration (FDA).
You means a person who manufac-
tures, packages, labels, or holds die-
tary supplements.
§ 111.5 Do other statutory provisions
and regulations apply?
In addition to this part, you must
comply with other applicable statutory
provisions and regulations under the
act related to dietary supplements.

Subpart B—Personnel
§ 111.8 What are the requirements
under this subpart B for written
procedures?
You must establish and follow writ-
ten procedures for fulfilling the re-
quirements of this subpart.

§ 111.10 What requirements apply for
preventing microbial contamination
from sick or infected personnel and
for hygienic practices?
(a) Preventing microbial contamination.
You must take measures to exclude
from any operations any person who
might be a source of microbial con-
tamination, due to a health condition,
where such contamination may occur,
of any material, including components,
dietary supplements, and contact sur-
faces used in the manufacture, pack-
aging, labeling, or holding of a dietary
supplement. Such measures include the
following:
(1) Excluding from working in any
operations that may result in contami-
nation any person who, by medical ex-
amination, the person’s acknowledge-
ment, or supervisory observation, is
shown to have, or appears to have, an
illness, infection, open lesion, or any
other abnormal source of microbial con-
tamination, that could result in mi-
crobial contamination of components,
dietary supplements, or contact sur-
faces, until the health condition no
longer exists; and
(2) Instructing your employees to no-
tify their supervisor(s) if they have or
if there is a reasonable possibility that
they have a health condition described
in paragraph (a)(1) of this section that
could result in microbial contamina-
tion of any components, dietary sup-
plements, or any contact surface.
(b) Hygienic practices. If you work in
an operation during which adulteration
of the component, dietary supplement,
or contact surface could occur, you
must use hygienic practices to the ex-
tent necessary to protect against such
contamination of components, dietary
supplements, or contact surfaces.
These hygienic practices include the
following:
(1) Wearing outer garments in a man-
ner that protects against the contami-
nation of components, dietary supple-
ments, or any contact surface;
(2) Maintaining adequate personal
cleanliness;
(3) Washing hands thoroughly (and
sanitizing if necessary to protect
against contamination with microorga-
nisms) in an adequate hand-washing fa-
cility:
(i) Before starting work; and
(ii) At any time when the hands may
have become soiled or contaminated;
(4) Removing all unsecured jewelry
and other objects that might fall into
components, dietary supplements,
equipment, or packaging, and removing
hand jewelry that cannot be ade-
quately sanitized during periods in
which components or dietary supple-
ments are manipulated by hand. If
hand jewelry cannot be removed, it
must be covered by material that is
maintained in an intact, clean, and
sanitary condition and that effectively
protects against contamination of
components, dietary supplements, or
contact surfaces;
(5) Maintaining gloves used in han-
dling components or dietary supple-
ments in an intact, clean, and sanitary
condition. The gloves must be of an im-
permeable material;
(6) Wearing, where appropriate, in an
effective manner, hair nets, caps, beard
covers, or other effective hair re-
straints;
(7) Not storing clothing or other per-
sonal belongings in areas where com-
ponents, dietary supplements, or any con-
tact surfaces are exposed or where con-
tact surfaces are washed;
(8) Not eating food, chewing gum,
drinking beverages, or using tobacco
products in areas where components,
dietary supplements, or any contact surfaces are exposed, or where contact surfaces are washed; and

(9) Taking any other precautions necessary to protect against the contamination of components, dietary supplements, or contact surfaces with microorganisms, filth, or any other extraneous materials, including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

§ 111.12 What personnel qualification requirements apply?

(a) You must have qualified employees who manufacture, package, label, or hold dietary supplements.

(b) You must identify who is responsible for your quality control operations. Each person who is identified to perform quality control operations must be qualified to do so and have distinct and separate responsibilities related to performing such operations from those responsibilities that the person otherwise has when not performing such operations.

(c) Each person engaged in manufacturing, packaging, labeling, or holding, or in performing any quality control operations, must have the education, training, or experience to perform the person’s assigned functions.

§ 111.13 What supervisor requirements apply?

(a) You must assign qualified personnel to supervise the manufacturing, packaging, labeling, or holding of dietary supplements.

(b) Each supervisor whom you use must be qualified by education, training, or experience to supervise.

§ 111.14 Under this subpart B, what records must you make and keep?

(a) You must make and keep records required under this subpart B in accordance with subpart P of this part.

(b) You must make and keep the following records:

(1) Written procedures for fulfilling the requirements of this subpart B; and

(2) Documentation of training, including the date of the training, the type of training, and the person(s) trained.

Subpart C—Physical Plant and Grounds

§ 111.15 What sanitation requirements apply to your physical plant and grounds?

(a) Grounds. You must keep the grounds of your physical plant in a condition that protects against the contamination of components, dietary supplements, or contact surfaces. The methods for adequate ground maintenance include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the physical plant so that it does not attract pests, harbor pests, or provide pests a place for breeding;

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where components, dietary supplements, or contact surfaces are exposed;

(3) Adequately draining areas that may contribute to the contamination of components, dietary supplements, or contact surfaces by seepage, filth or any other extraneous materials, or by providing a breeding place for pests;

(4) Adequately operating systems for waste treatment and disposal so that they do not constitute a source of contamination in areas where components, dietary supplements, or contact surfaces are exposed; and

(5) If your plant grounds are bordered by grounds not under your control, and if those other grounds are not maintained in the manner described in this section, you must exercise care in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth or any other extraneous materials that may be a source of contamination.

(b) Physical plant facilities. (1) You must maintain your physical plant in a clean and sanitary condition; and

(2) You must maintain your physical plant in repair sufficient to prevent components, dietary supplements, or contact surfaces from becoming contaminated.

(c) Cleaning compounds, sanitizing agents, pesticides, and other toxic materials. (1) You must use cleaning compounds and sanitizing agents that are free from microorganisms of public