**Section 720.50 Drugs and Devices**

a) Drugs: Name.

The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

b) The term "drug defined in an official compendium" means a drug having the identity prescribed for a drug in an official compendium.

c) A statement that a drug defined in an official compendium differs in strength, quality or purity from the standard of strength, quality or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.

d) Drugs and Devices: Labeling, Misbranding.

Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or a food or cosmetic.

e) The labeling of a drug which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

f) Drugs and Devices: Place of Business.

If a drug or device is not manufactured by the person whose name appear on the label, the name shall be qualified by a phrase which reveals the connection such person has with such drug or device, such as "Manufactured for and Packed by \_\_\_\_\_\_\_\_\_\_\_\_," "Distributed by \_\_\_\_\_\_\_\_\_\_\_\_," or other similar phrase which expresses the facts.

g) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

h) Where a person manufactures, packs or distributes a drug or device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such drug or device was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

i) The requirement that the label shall contain the name and place of business of the manufacturer, packer or distributor shall not be considered to relieve any drug or device from the requirement that its label shall not be misleading in any particular.

j)

1) The statement of the quantity of the contents of a package of a drug shall reveal the quantity of such drug in the package, exclusive of wrappers and other material packed with such drug.

2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers and users of such drug to express quantity thereof and which give accurate information as to such quantity. But if no general usage in expressing accurate information as to the quantity of such drug exists among consumers and users thereof, the statement of the quantity of a drug which is not in tablet, capsule, ampule or other unit form shall be in terms of weight if the drug is solid, semisolid or viscous, or in terms which if in such unit form shall be in terms of the numerical count of such units, supplemented, when necessary to give accurate information as to the quantity of such drug in the package, by such statement (in such terms, manner and form as are not misleading) of the weight or measure of such units, or of the quantity of each active ingredient in each such unit as will give such information.

k) The statement of the quantity of a device shall be expressed in terms of numerical count.

l) A statement of weight shall be in terms of the avoirdupois pound, ounce and grain, or of the kilogram, gram and milligram. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, fluid ounce and fluid dram subdivisions thereof, or of the liter, milliliter or cubic centimeter, and shall express the volume at 68º Fahrenheit (20º Centigrade).

m) Statements of the quantity of a drug shall contain only such fractions as are generally used in expressing the quantity of such drug. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

n)

1) Unless made in accordance with the provisions of subsection (n)(2) of this Section, a statement of the quantity of a drug, in the terms of weight or measure applicable to such drug under the provisions of subsection (j)(2) of this Section, shall express the number of the largest unit specified in subsection (l) of this Section which is contained in the package (for example, the statement on the label of a package which contains one pint of a drug shall be "1 pint" and not "16 fluid ounces"). Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in subsection (l) of this Section (for example, 1¼ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in subsection (l) of this Section) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for example, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint").

2) In the case of a drug with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

o) The statement of the quantity of a drug or device shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement, except in the case of ampules, shall be considered to express the average quantity. The statement of the quantity of a drug in ampules shall be considered to express the minimum quantity.

p) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure of a drug caused by ordinary and customary exposure, after such drug is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large. In the case of a liquid drug in ampules the variation above the stated measure shall comply with the excess volume prescribed by the National Formulary for filling of ampules.

q) Where the statement does not express the minimum quantity:

1) Variations from the stated weight or measure of a drug shall be permitted when caused by ordinary and customary exposure after such drug is introduced into commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

2) Variations from the stated weight, measure or numerical count of a drug or device shall be permitted when caused by unavoidable deviations in weighing, measuring or counting the contents of individual packages which occur in good packing practice. But, under this paragraph, variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the drug or device is below the quantity stated and no unreasonable shortage in any package shall be permitted, even though coverages in other packages in the same shipment or delivery compensate for such shortage.

r) The extent of variations from the stated quantity of the contents permissible under subsections (p) and (q) of this Section in the case of each shipment or other delivery shall be determined by the facts in such case.

s) A drug or device shall be exempt from compliance with the requirements of Section 15(b)(2) of the Act if:

1) The statement of the quantity of the contents, as expressed in terms applicable to such drug or device under the provisions of subsection (j)(2) of this Section, together with all other words, statements and information required by or under authority of the Act to appear on the label of such drug or device, cannot, because of insufficient label space, be so placed on the label as to comply with requirements of Section 15(c) of the Act and regulations promulgated thereunder, or

2) The quantity of the contents of the package, as expressed in terms of numerical count in compliance with subsections (l)(2) or (m) of this Section is less than six units, and such units can be easily counted without opening the package, or

3) It is an ointment, is labeled "Sample" or "Physician's Sample," or with a substantially similar statement, and the contents of the package do not weigh more than 8 grams.

t) Drugs and Devices: Forms of Making Required Statements.

A word, statement or other information required by or under authority of the Act to appear on the label may lack that prominence and conspicuousness required by Section 15(c) of the Act by reason (among other reasons) of:

1) The failure of such word, statement or information to appear on the part or panel of the label which is presented or displayed under customary conditions of the purchase;

2) The failure of such word, statement or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement or information;

4) Insufficiency of label space (for the prominent placing of such word, statement or information) resulting from the use of label space for any word, statement, design or device which is not required by or under authority of the Act to appear on the label;

5) Insufficiency of label space (for the prominent placing of such word, statement or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement or information, or to any design or device; or

6) Smallness or style of type in which such word, statement or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed or graphic matter.

u) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under Section 15(b) or (e) of the Act, shall apply if such insufficiency is caused by:

1) The use of label space for any word, statement, design or device which is not required by or under authority of the Act to appear on the label;

2) The use of label space to give greater conspicuousness to any word, statement or other information than is required by Section 15(c) of the Act; or

3) The use of label space for any representation in a foreign language.

v)

1) All words, statements and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language;

2) If the label contains any representation in a foreign language, all words, statement and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language;

3) If the labeling contains any representation in a foreign language, all words, statements and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

w) Drugs: Statement of Ingredients.

The ingredient information required by Section 15(e) of the Act shall appear together, without any intervening written, printed or graphic matter, except the proprietary names of ingredients, which may be included with the listing of established names, and such statements as "Warning – May be Habit Forming" that are specifically required for certain ingredients by the Act or regulations promulgated thereunder.

x) The term "ingredient" applies to any substance in the drug, whether added to the formulation as a single substance or in admixture with other substances.

y) The labeling of a drug may be misleading by reason (among other reasons) of:

1) The order in which the names of the ingredients present in the drug appear in the labeling, or the relative prominence otherwise given such names;

2) Failure to reveal the proportion of, or other fact with respect to, an ingredient present in such drug, when such proportion or other fact is material in the light of the representation that such ingredient is present in such drug;

3) The employment of a fanciful proprietary name for a drug or ingredient in such a manner as to imply that the drug or ingredient has some unique effectiveness or composition when, in fact, the drug or ingredient is a common substance, the limitations of which are readily recognized when the drug or ingredient is listed by its established name;

4) The featuring in the labeling of inert or inactive ingredients in a manner that creates an impression of value greater than their true functional role in the formulation;

5) Designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.

z)

1) If the drug is in tablet or capsule form or other unit dosage form, any statement of the quantity of an ingredient contained therein shall express the quantity of such ingredient in each such unit. If the drug is not in unit dosage form, any statement of the quantity of an ingredient contained therein shall express the amount of such ingredient in a specified unit of weight or measure of the drug, or the percentage of such ingredient in such drug. Such statements shall be in terms that are informative to licensed practitioners, in the case of a prescription drug, and to the layman, in the case of a nonprescription drug.

2) A statement of the percentage of an ingredient in a drug shall, if the term "percent" is used without qualification, mean percent weight-in-weight, if the ingredient and the drug are both solids, or if the ingredient is a liquid and the drug is a solid; percent weight-in-volume at 68º F. (20º C.), if the ingredient is a solid and the drug is a liquid; and percent volume-in-volume at 68º F. (20º C.), if both the ingredient and the drug are liquids, except that alcohol shall be stated in terms of percent volume of absolute alcohol at 60º F. (15.56º C.).

aa) A derivative or preparation of a substance named in Section 15(c) of the Act is an article derived or prepared from such substance by any method, including actual or theoretical chemical action.

bb) If an ingredient is a derivative or preparation of a substance specifically named in Section 15(e) of the Act and the established name of such ingredient does not indicate that it is a derivative or preparation of the parent substance named in Section 15(e) of the Act, the labeling shall, in conjunction with the listing of the established name of such ingredient, declare that such article is a derivative or preparation of such parent substance.

cc)

1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as "brand of," preceding the established name, or by brackets surrounding the established name.

2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is jointed, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast and other printing features.

dd)

1) In the case of a prescription drug containing two or more active ingredients, if the label bears a proprietary name or designation for such mixture and there is no established name corresponding to such proprietary name or designation, the quantitative ingredient information required on the label by Section 15(e) of the Act shall be placed in direct conjunction with the most prominent display of the proprietary name or designation. The prominence of the quantitative ingredient information shall bear a reasonable relationship to the prominence of the proprietary name.

2) If the drug is packaged in a container too small to bear the quantitative ingredient information on the main display panel, the quantitative ingredient information required by Section 15(e) of the Act may appear elsewhere on the label, even thought the proprietary name or designation appears on the main display panel of the label; but side-or-back-panel placement shall in this case be so arranged and printed as to provide size and prominence of display reasonably related to the size and prominence of the front-panel display.

ee) A drug packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with Section 15(e)(1)(ii) of the Act shall be exempt from compliance with those clauses; Provided that:

1) The label bears:

A) The proprietary name of the drug;

B) The established name, if such there be, of the drug;

C) An identifying lot or control number; and

D) The name of the manufacturer, packer or distributor of the drug; AND

2) All the information required to appear on the label by the Act and the regulations promulgated thereunder appears on the carton or other outer container or wrapper if such carton, outer container or wrapper has sufficient space to bear such information, or such complete label information appears on a leaflet with the package.

ff) Prescription: Drug Advertisements.

All advertisements for prescription drugs shall be subject to all regulations issued under the Federal Food, Drug and Cosmetic Act (the Federal Act), as amended (21 U.S.C. 352), including all regulations relating to but not limited to Section 502(n) of such Federal Act.

gg) An advertisement issued or caused to be issued by the manufacturer, packer or distributor of the drug promoted by the advertisement and which is not in compliance with Section 502(n) of the Federal Food, Drug and Cosmetic Act (the Federal Act), as amended (21 U.S.C. 352), and the applicable regulations thereunder shall cause stocks of such drug in possession of the person responsible for issuing or causing the issuance of the advertisement, and stocks of the drug distributed by such person and still in the channels of commerce, to be misbranded under Section 15(n) of the Act.

hh) Brochures, mailing pieces, detailing pieces, file cards, bulletins, price lists, catalogs, house organs, literature reprints and similar pieces of printed matter concerning a drug and which are disseminated by or on behalf of its manufacturer, packer or distributor, including reference publications for use by medical practitioners, pharmacists or nurses, containing drug information supplied by the manufacturer, packer or distributor of the drug, are regarded as labeling not subject to Section 15(n) of the Act but subject to the labeling requirement of subsections (w) through (ee) inclusive and subsections (ii) through (vv) inclusive of this Section.

ii) Drugs and Devices: Directions For Use.

ADEQUATE DIRECTIONS FOR USE. "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

1) Statements of all conditions, purposes or uses for which such drug or device is intended, including conditions, purposes or uses for which it is prescribed, recommended or suggested in its oral, written, printed or graphic advertising, and conditions, purposes or uses for which the drug or device is commonly used; except that such statements shall not refer to conditions, uses or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

2) Quantity of dose (including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions).

3) Frequency of administration or application.

4) Duration of administration or application.

5) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors).

6) Route of method of administration or application.

7) Preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

jj) Exemption for Prescription Drugs.

A drug subject to the requirements of Section 16(a) of the Act shall be exempt from Section 15(f)(1) if all the following conditions are met:

1) The drug is:

A)

i) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage or wholesale distribution of prescription drugs; or

ii) In the possession of a retail, hospital or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs; or

iii) In the possession of a practitioner licensed by law to administer or prescribe such drugs; and

B) It is to be dispensed in accordance with Section 16 of the Act.

2) The label of the drug bears:

A) The statement "Caution: Federal law prohibits dispensing without prescription" or "Caution: State law prohibits dispensing without prescription"; and

B) The recommended or usual dosage; and

C) The route of administration, if it is not for oral use; and

D) The quantity or proportion of each active ingredient, as well as the information required by Section 15(d) and (e) of the Act; and

E) If it is for other than oral use, the names of all inactive ingredients, except that:

i) Flavorings and perfumes may be designated as such without naming their components;

ii) Color additives may be designated as coloring without naming specific color components unless the naming of such components is required by a color additive regulation adopted under the Federal Act;

iii) Trace amounts of harmless substances added solely for individual product identification need not be named;

F) If it is intended for administration by parenteral injection, the quantity of proportion of all inactive ingredients, except that ingredients added to adjust the pH or to make the drug isotonic may be declared by name and a statement of their effect; and if the vehicle is water for injection it need not be named;

G) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug;

H) Provided, however, that in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, but which are packaged within an outer container from which they are removed for dispensing or use, the information required by subsections (jj)(2)(B), (C) and (E) above may be contained in other labeling on or within the package from which it is to be dispensed, and the information referred to in subsection (jj)(2)(A) above may be placed on such outer container only, and the information required by subsection (jj)(2)(G) above may be on the crimp of the dispensing tube.

3)

A) Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administrations, and any relevant hazards, contraindications, side effects and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented; and

B) If the article is subject to Section 17 of the Act or Section 506 or 507 of the Federal Act, the labeling bearing such information is the labeling authorized by the approved new-drug application or required as a condition for the certification or the exemption from certification requirements applicable to preparations of insulin or antibiotic drugs: Provided, however, that the information required by subsection (jj)(3)(A) above may be omitted from the dispensing package if, but only if, the article is a drug for which directions, hazards, warnings, and use information are commonly known to practitioners licensed by law to administer the drug. Upon written request, stating reasonable grounds therefor, the Director will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

4) Any labeling, as defined in Section 1.10 of the Act, whether or not it is on or within a package from which the drug is to be dispensed, distributed by or on behalf of the manufacturer, packer or distributor of the drug, that furnishes or purports to furnish information for use or which prescribes, recommends or suggests a dosage for the use of the drug (other than dose information required by subsection (jj)(2)(B) and subsection (kk) of this Section) contains:

A) Adequate information for such use, including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects and precautions, under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all conditions for which it is advertised or represented; and if the article is subject to Section 15 of the Act or Section 506 or 507 of the Federal Act, the labeling providing such information is substantially the same as the labeling authorized by the approved new-drug application or required as a condition for its certification, or exemption from certification; and

B) The same information concerning the ingredients of the drug as appears on the label and labeling on or within the package from which the drug is to be dispensed; Provided, however, that the information required by subsections (jj)(4)(A) and (B) of this Section is not required on the so-called reminder-piece labeling which calls attention to the name of the drug but does not include indications or dosage recommendations for use of the drug.

5) All labeling, except labels and cartons, bearing information for use of the drug also bears the date of the issuance or the date of the latest revision of such labeling.

kk) Exemption for Veterinary Drugs.

A drug intended for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from Section 15(f)(1) of the Act if all the following conditions are met:

1) The drug is:

A) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage or wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice; or

B) In the possession of a licensed veterinarian for use in the course of his professional practice.

2) The label of the drug bears:

A) The statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian" or "Caution: State law restricts this drug to sale by or on the order of a licensed veterinarian"; and

B) The recommended or usual dosage; and

C) The route of administration, if it is not for oral use; and

D) The quantity or proportion of each active ingredient as well as the information required by Section 15(e) of the Act; and

E) If it is for other than oral use, the names of all inactive ingredients, except that:

i) Flavorings and perfumes may be designated as such without naming their components;

ii) Color additives may be designated as coloring without naming specific color components unless the naming of such components is required by a color additive regulation adopted under the Federal Act;

iii) Trace amounts of harmless substances added solely for individual product identification need not be named;

F) If it is intended for administration by parenteral injection, the quantity of proportion of all inactive ingredients, except that ingredients added to adjust the pH or to make the drug isotonic may be declared by name and a statement of their effect; and if the vehicle is water for injection it need not be named;

G) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug; Provided, however, that in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, but which are packaged within an outer container from which they are removed for dispensing or use, the information required by subsections (kk)(2)(B), (C) and (E) above may be contained in other labeling on or within the package from which it is to be so dispensed, and the information referred to in subsection (kk)(2)(A) above may be placed on such outer container only, and the information required by this subsection (kk)(2)(G) may be on the crimp of the dispensing tube.

3)

A) Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administrations, and any relevant hazards, contraindications, side effects and precautions under which veterinarians licensed by law to administer the drug can use the drug safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented; and

B) If the article is subject to Section 17 of the Act or Section 507 of the Federal Act, the labeling bearing such information is the labeling authorized by the approved new-drug application or required as a condition for the certification or the exemption from certification requirements applicable to preparations of antibiotic drugs: Provided, however, that the information required by subsection (kk)(3)(A) above may be omitted from the dispensing package if, but only if, the article is a drug for which directions, hazards, warnings, and use information are commonly known to veterinarians licensed by law to administer the drug. Upon written request, stating reasonable grounds therefor, the Director will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

4) Any labeling, as defined in Section 2.10 of the Act, whether or not it is on or within a package from which the drug is to be dispensed, distributed by or on behalf of the manufacturer, packer or distributor of the drug, that furnishes or purports to furnish information for use or which prescribes, recommends or suggests a dosage for the use of the drug (other than dose information required by subsection (kk)(2)(B) and subsection (ll) of this Section) contains:

A) Adequate information for such use, including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects and precautions, and including information relevant to compliance with the food additive provisions of the Act, under which veterinarians licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all conditions for which it is advertised or represented; and if the article is subject to Section 17 of the Act or Section 507 of the Federal Act, the labeling providing such information is substantially the same as the labeling authorized by the approved new-drug application or required as a condition for its certification, or exemption from certification; and

B) The same information concerning the ingredients of the drug as appears on the label and labeling on or within the package from which the drug is to be dispensed; Provided, however, that the information required by subsections (kk)(4)(A) and (B) of this Section is not required on the so-called reminder-piece labeling which calls attention to the name of the drug but does not include indications or dosage recommendations for use of the drug.

5) All labeling, except labels and cartons, bearing information of use of the drug also bears the date of the issuance or the date of the latest revision of such labeling.

6) A prescription drug intended for both human and veterinary use shall comply with subsections (z) and (kk)(4) and (5) of this Section.

ll) Exemption for Prescription Devices.

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from Section 15(f)(1) of the Act if all the following conditions are met:

1) The device is:

A)

i) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage or wholesale or retail distribution of such device; or

ii) In the possession of a practitioner, such as physicians, dentists and veterinarians, licensed by law to use or order the use of such device; and

B) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his practice.

2) The label of the device (other than surgical instruments) bears:

A) The statement "Caution: Federal law restricts this device to sale by or on the order of a \_\_\_\_\_\_\_\_\_\_\_" or "Caution: State law restricts this device to sale by or on the order of a \_\_\_\_\_\_\_\_\_\_\_," the blank to be filled with the word "physician," "dentist," "veterinarian," or with the descriptive designation of any other practitioner licensed by law of the State to use or order the use of the device; and

B) The method of its application or use.

3) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: Provided, however, that such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Director will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

4) Any labeling, as defined in Section 2.10 of the Act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented. This information will not be required on so-called reminder-piece labeling which calls attention to the name of the device but does not include indications or other use information.

5) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

mm) Exemption for Retail Veterinary Drugs and Prescription Devices.

A drug or device subject to subsections (kk) or (ll) of this Section shall be exempt at the time of delivery to the ultimate purchaser or user from Section 15(f)(1) of the Act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

nn) Exemption for New Drugs.

A new drug shall be exempt from Section 15(f)(1) of the Act:

1) To the extent to which such exemption is claimed in an approved application with respect to such drug under Section 17 of the Act; or

2)

A) If no application under Section 17 of the Act is approved with respect to such drug but it complies with Section 505(i) of the Federal Act and regulations thereunder.

B) No exemption shall apply to any other drug which would be a new drug if its labeling bore representations for its intended use.

oo) Exemption For Drugs or Devices When Directions Are Commonly Known.

A drug or device shall be exempt from Section 15(f)(1) of the Act insofar as adequate directions for common uses thereof are known to the ordinary individual.

pp) Exemptions For Inactive Ingredients.

A harmless drug that is ordinarily used as an inactive ingredient, such as coloring, emulsifier, excipient, flavoring, lubricant, preservative or solvent, in the preparation of other drugs, shall be exempt from Section 15(f)(1) of the Act. This exemption shall not apply to any substance intended for a use which results in the preparation of a new drug, unless an approved new-drug application provides for such use.

qq) Exemption for Diagnostic Reagents.

A drug intended solely for use in the professional diagnosis of disease and which is generally recognized by qualified experts as useful for that purpose shall be exempt from Section 15(f)(1) of the Act if it label bears the statement "Diagnostic reagent – For professional use only."

rr) Exemption for Prescription Chemicals and Other Prescription Components.

A drug prepared, packaged and primarily sold as a prescription chemical or other component for use by registered pharmacists in compounding prescriptions or for dispensing in dosage unit form upon prescriptions shall be exempt from Section 15(f)(1) of the Act if all the following conditions are met:

1) The drug is an official liquid acid or official liquid alkali or is not a liquid solution, emulsion, suspension, tablet, capsule or other dosage unit form; and

2) The label of the drug bears:

A) The statement "For prescription compounding," and

B) If in substantially all dosage forms in which it may be dispensed it is subject to Section 16(a) of the Act, the statement "Caution: Federal law prohibits dispensing without prescription" or "Caution: State law prohibits dispensing without prescription," or

C)

i) If it is not subject to Section 16(a) of the Act and is by custom among retail pharmacists sold in or from the interstate package for use by consumers, "adequate directions for use" in the conditions for which it is so sold.

ii) Provided, however, that the information referred to in subsection (rr)(2)(C)(i) above may be contained in the labeling on or within the package from which it is to be dispensed.

3) This exemption shall not apply to any substance intended for use in compounding which results in a new drug, unless an approved new-drug application covers such use of the drug in compounding prescriptions.

ss) Exemption for Processing, Repacking or Manufacture.

A drug in a bulk package (except tablets, capsules or other dosage unit forms) or a device intended for processing, repacking or use in the manufacture of another drug or device shall be exempt from Section 15(f)(1) of the Act if its label bears the statement "Caution: For manufacture, processing or repacking" and, if in substantially all dosage forms in which it may be dispensed it is subject to Section 16(a) of the Act, the statement "Caution: Federal law prohibits dispensing without prescription" or "Caution: State law prohibits dispensing without prescription." This exemption and the exemption under subsection (rr) of this Section may be claimed for the same article. But the exemption shall not apply to a substance intended for a use in manufacture, processing or repacking which causes the finished article to be a new drug, unless:

1) An approved new-drug application held by the person preparing the dosage form or drug for dispensing covers the production and delivery to him of such substance; or

2) If no application is approved with respect to such new drug, the label statement "Caution: For manufacturing, processing or repacking" is immediately supplemented by the words "in the preparation of a new drug limited by Federal law to investigational use" or "in the preparation of a new drug limited by Illinois law to investigational use," and the delivery is made for use only in the manufacture of such new drug limited to investigation use.

tt) Exemption For Drugs and Devices For Use in Teaching, Law Enforcement, Research and Analysis.

A drug or device subject to subsections (jj), (kk) or (ll) of this Section shall be exempt from Section 15(f)(1) of the Act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, law enforcement, research, analysis or testing.

uu) Expiration of Exemptions.

1) If a shipment or delivery, or any part, of a drug or device which is exempt under the regulations in this Section is made to a person in whose possession the article is not exempt, or is made for any purpose other than those specified, such exemption shall expire, with respect to such shipment or delivery or part, at the beginning of that shipment or delivery. The causing of an exemption to expire shall be considered an act which results in such drug or device being misbranded unless it is disposed of under circumstances in which it ceases to be a drug or device.

2) The exemptions conferred by subsections (pp), (qq), (rr), (ss) and (tt) of this Section shall continue until the drugs or devices are used for the purposes for which they are exempted, or until they are relabeled to comply with Section 15(f)(1) of the Act. If, however, the drug is converted, compounded or manufactured into a dosage form limited to prescription dispensing, no exemption shall thereafter apply to the article unless the dosage form is labeled as required by Section 16 of the Act and subsections (jj), (kk) or (ll) of this Section.

vv) Intended Uses.

The words "intended uses" or words of similar import in subsections (ii), (nn), (pp), (qq), (rr) and (ss) of this Section refer to the objective intent of the persons legally responsible for the labeling of drugs and devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into commerce by its manufacturer. If, for example, a packer, distributor or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug or device introduced into commerce by him is to be used for conditions, purposes or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

ww) Drugs and Devices: Exemptions.

1) Except as provided by subsections (ww)(2) and (3) below, a shipment or other delivery of a drug or device which is, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of Sections 14(b) and 15(b), (d), (e), (f) and (g) of the Act if:

A) The person who introduced such shipment or delivery into commerce is the operator of the establishment where such drug or device is to be processed, labeled or repacked; or

B) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling or repacking, as the case may be, of such drug or device in such establishment as will insure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling or repacking. Such person and such operator shall each keep a copy of such agreement until two years after the final shipment or delivery of such drug or device from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Illinois Department of Public Health who requests them.

2) An exemption of a shipment or other delivery of a drug or device under subsection (ww)(1)(A) above shall, at the beginning of the act of removing such shipment or delivery, or any part, from such establishment, become void ab initio if the drug or device comprising such shipment, delivery, or part, is adulterated or misbranded within the meaning of the act when so removed.

3) An exemption of a shipment or other delivery of a drug or device under subsection (ww)(1)(B) above shall become void ab initio with respect to the person who introduced such shipment or delivery into commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such subsection.

4) An exemption of a shipment or other delivery of a drug or device under subsection (ww)(1)(B) above shall expire:

A) At the beginning of the act of removing such shipment or delivery, or any part, from such establishment if the drug or device comprising such shipment, delivery, or part, is adulterated or misbranded within the meaning of the act when so removed; or

B) Upon refusal by the operator of the establishment where such drug or device is to be processed, labeled or repacked, to make available for inspection a copy of the agreement, as required by such clause.

5) Except as provided in subsections (ww)(7) and (8) below, a shipment or other delivery of a drug which is subject to Section 507 of the Federal Act and which is, in accordance with the practice of the trade, other than that where originally processed or packed, shall be exempt from compliance with the labeling requirements of Section 15(f) of the Act during the time such drug is also exempt from the requirements of Section 15(1) of the Act.

6) Except as provided by subsections (ww)(7) and (8) below, a shipment or other delivery of a drug which is subject to Section 507 of the Federal Act and which is, in accordance with the practice of the trade, to be labeled in substantial quantity at an establishment other than that where originally processed or packed shall be exempt from compliance with the labeling requirements of Section 15(b), (e) and (f) of the Act during the time such drug is also exempt from the requirements of Section 15(1) of the Act if the words, statements and other information required by Section 15(b) and (e) of the Act appear on each shipping container of such drug.

7) In case the person who introduced such shipment or other delivery into commerce is the operator of the establishment where such drug is to be processed, labeled or repacked, an exemption of such shipment or delivery under subsections (ww)(5) and (6) above shall become void at the beginning of the act or removing such shipment or delivery or any part from such establishment if the drug comprising such shipment, delivery, or part, is adulterated or misbranded within the meaning of the act when so removed.

8) In case the person who introduced such shipment or delivery into interstate commerce is not the operator of the establishment where such drug is to be processed, labeled or repacked, an exemption of a shipment or other delivery of such drug under subsections (ww)(5) and (6) above shall expire at the beginning of the act or removing such shipment or delivery or any part from such establishment if the drug comprising such shipment, delivery, or part, is adulterated or misbranded within the meaning of the act when so removed.

xx) Definition of Term "Insulin."

For the purposes of Section 15(k) of the Act and Section 506 of the Federal Act.

1) The term "insulin" as used therein means the active principle of pancreas which affects the metabolism of carbohydrates in the animal body and which is of value in the treatment of diabetes mellitus.

2) The following substances, when they are intended for use in the manufacturing of insulin-containing drugs that will subsequently be submitted for certification, shall not be considered to be subject to certification as "drugs composed wholly or partly of insulin":

A) Pancreas glands; and

B) Materials prepared from pancreas glands, such as "sale cake" and "isoelectric precipitate," which materials must be subjected to further purification in order to meet the standards of purity established by 21 CFR 429 of the Federal Regulations.