STATE OF MAINE
DEPARTMENT OF ENVIRONMENTAL PROTECTION

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Background Information for Producer Exemptions

In preparation for discussions regarding producer exemptions, the Department of Environmental Protection ("Department") has reviewed the federal laws and regulations identified in paragraph 13(D), subparagraphs 1-4 of the Packaging Stewardship Law (38 M.R.S. § 2146(13)(D)(1-4)). This background document includes excerpts from the Packaging Stewardship Law, "Drug take-back stewardship program" (38 M.R.S. § 1612), the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. ch. 9, § 301 et seq.), the Federal Poison Prevention Packaging Act of 1970 (PPPA) (15 U.S.C. ch. 39A, § 1471 et seq.), and their accompanying regulations along with summary of relevant requirements from the Department. Links to the federal law and regulations reviewed by the Department are listed below:

- Section 321 of the federal Food, Drug, and Cosmetic Act
- United States Food and Drug Administration under 21 Code of Federal Regulations
  - Part 200
  - Part 300
  - Part 800
- Poison Prevention Packaging Act of 1970

While we welcome all relevant information; the Department is particularly interested in hearing comments that speak to the following:

- Is the description of perishable food under subsection 2 sufficient (38 M.R.S. § 2146(2))? If the description of perishable food under subsection 2 is not sufficient, please suggest how it might be further described or clarified.
- Which products, if any, should be exempt under paragraph 13(D) (38 M.R.S. § 2146(13)(D)? If you propose a subset of products should be exempt, please provide information justifying why those products should be exempt, including information on the way federal regulations limit the producer's ability to increase the recyclability and/or decrease the amount of packaging used.
- Which biological products have packaging as defined by the Packaging Stewardship Law (38 M.R.S. § 2146(13)(D)(2))?
- If you believe we have omitted a federal requirement that limits the producer's ability to increase the recyclability or decrease the amount of packaging used, please provide clarifications, corrections, or additions.

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Background information – Perishable Food Exemptions

The Packaging Stewardship Law **exempts producers of perishable food** from regulation,

> *...in any calendar year in which […] the producer sold, offered for sale or distributed for sale in or into the State during the prior calendar year to retailers or direct to consumers products that were perishable food and that were contained, protected, delivered, presented or distributed in or using less than 15 tons of packaging material in total.* (38 M.R.S. § 2146(2)(D))
>
> *...as used in this paragraph, "perishable food" means any food that may spoil or otherwise become unfit for human consumption because of its nature, type or physical conditions, including, but not limited to, fresh and processed meats, poultry, seafood, dairy products, bakery products, eggs in the shells and fresh fruits and vegetables. "Perishable food" does not include any such food that is sold, offered for sale or distributed for sale frozen except for frozen wild blueberries.* (38 M.R.S. § 2146(2))

The Packaging Stewardship Law **defines packaging material** as follows,

> *"Packaging material" means a discrete type of material, or a category of material that includes multiple discrete types of material with similar management requirements and similar commodity values, used for the containment, protection, delivery, presentation or distribution of a product, including a product sold over the Internet, at the time that the product leaves a point of sale with or is received by the consumer of the product. "Packaging material" does not include a discrete type of material, or a category of material that includes multiple discrete types of material, that is:*
>
> 1. *Intended to be used for the long-term storage or protection of a durable product and that can be expected to be usable for that purpose for a period of at least 5 years;*
> 2. *A beverage container, as defined in section 3102, subsection 2, subject to the requirements of chapter 33;*
> 3. *A container for architectural paint, as defined in section 2144, subsection 1, paragraph A, as long as a paint stewardship program is in operation, has been approved by the department pursuant to section 2144 and the stewardship organization operating that program:*
>   *(a) Has demonstrated to the department's satisfaction that it recycles at least 90% of the containers of architectural paint collected under the program; or*
>   *(b) Subject to the approval of the department, if unable to satisfy the requirements of division (a), has demonstrated to the department's satisfaction that it recycles at least 80% of the containers of architectural paint collected under the program; or*
> 4. *Excluded from the definition of "packaging material" by the department by rule adopted pursuant to subsection 13, paragraph D.* (38 M.R.S. § 2146(1)(I))

Background Information – Federally Regulated Products

The Food and Drug Administration (FDA) regulates the packaging material of some products. The Packaging Stewardship Law requires the Department review the packaging material of certain federally regulated products to determine whether it should be excluded from the definition of packaging material and **puts forth the following instruction with regards to this determination**,

> *…in making such a determination, the department shall, at a minimum, consider whether the packaging material for such products is required by federal law or regulation to meet specific content or construction standards that may preclude or significantly diminish the producer's ability to increase the recyclability or reduce the volume of the packaging material.* (38 M.R.S. § 2146(13)(D))

The Packaging Stewardship Law requires the department to review the packaging material associated with the following federally regulated products:

1. *Material that is used for the containment, protection, delivery, presentation or distribution of a drug, as that term is defined under Section 321 of the federal Food, Drug, and Cosmetic Act, as regulated by the United States Food and Drug Administration under the federal Food, Drug, and Cosmetic Act or as collected under a stewardship program in the State that has been approved for operation by the department and has been established to collect and dispose of such drugs, including, but not limited to, prescription and nonprescription drugs, drugs in medical devices and combination products, branded and generic drugs and drugs for veterinary use;*
2. *Material that is a medical device or a biological product, or is used for the containment, protection, delivery, presentation or distribution of a medical device or a biological product, as regulated by the United States Food and Drug Administration under 21 Code of Federal Regulations, Parts 200, 300 and 800;*
3. *Material that is used for the containment, protection, delivery, presentation or distribution of an over-the-counter human drug product for which tamper-evident packaging is required, as regulated by the United States Food and Drug Administration under 21 Code of Federal Regulations, Section 211.132; and*
4. *Material that is used for the containment, protection, delivery, presentation or distribution of a substance regulated by the United States Consumer Product Safety Commission pursuant to the federal Poison Prevention Packaging Act of 1970 for which special packaging is required under 16 Code of Federal Regulations, Part 1700.* (38 M.R.S. § 2146(13)(D)(1-4))

The Department's summary of relevant information regarding each of the federally regulated products mentioned above is as follows:

1-A. Material that is used for the containment, protection, delivery, presentation or distribution of a drug

How is drug defined? A summary of how 21 U.S.C. § 321(g)(1) of the FFDCA **defines a drug** as—

1. *articles recognized by any supplement to the United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States and National Drug Formulary, and*
2. *articles intended for use in diagnostics, cure, mitigation, treatment or prevention of disease in man or animal, and*
3. *articles, other than food, intended to affect structure or function of the body of man or animal, and*
4. *articles intended for use as component of any of the articles defined above.*

This definition includes both prescription and over the counter (OTC) drug products.

Some examples of OTC drug products:

- antiseptic soaps and cleansers, such as acne washes and treatments
- hand antiseptic and disinfectants, such as hand sanitizers
- topical antiseptics, such as alcohols and hydrogen peroxide
- topical and oral analgesics
- antiperspirants, such as deodorants and lotions
- oral antiseptic rinses
- fluoride toothpaste
- medicated lip balm
- topical antihistamines
- antifungals
- antidandruff and lice-repelling shampoos
- hair growth products with approved chemical agents
- sunscreens
- cosmetics with sun-protectant claims
- therapeutic throat lozenges
- smoking cessation drugs
- pesticide products for animals

What are the FDA packaging requirements for drug products? During review, the Department did not identify any federal packaging requirements for drug products that may affect a producer's ability to improve the recyclability and/or reduce the volume of packaging material. However, some specific classes of drugs have packaging requirements that may affect the recyclability and/or amount of packaging. For example, 21 C.F.R. Part 200.50 Subpart C states the following about ophthalmic preparation and dispensers:

Eye cups, eye droppers, and other dispensers intended for ophthalmic use should be sterile, and may be regarded as falling below their professed standard of purity or quality if they are not sterile. These articles, which are regulated as drugs if packaged with the drugs with which they are to be used, should be packaged so as to maintain sterility until the package is opened and be labeled, on or within the retail package, so as to afford adequate directions and necessary warnings to minimize the hazard of injury resulting from contamination during use.

The Department is seeking additional information on the extent to which these requirements affect the amount and/or recyclability of packaging for specific classes of drug products. Should a regulation specific to a class of drug products affects the amount and/or recyclability of packaging, please bring it to our attention.

What are the FDA labeling requirements for drug products? During review, the Department did identify relevant labeling requirements that may affect a producer's ability to improve the recyclability and/or reduce the volume of packaging material.

The FDA's definition of labeling includes labels on the immediate container of any article, and written, printed or graphic material accompanying an article.

How is label defined? 21 U.S.C. § 321 (k) **defines a label** as—

a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

How is labeling defined? 21 U.S.C. § 321(m) of the FFDCA **defines labeling** as—

all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

Some examples.

- Posters
- Tags
- Pamphlets
- Circulars
- Booklets
- Brochures
- Instruction sheets
- Direction sheets
- Fillers

What must be included on the label of a drug product? 21 U.S.C. § 352 outlines labeling requirements and states—

A drug or device shall be deemed to be misbranded- […]

> *(b) Package form; contents of label*
> *If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.*

The Department did not identify other labeling contents that need to appear on the label of the package for drug products acknowledging the labeling requirements for prescription drug products and/or insulin differ from those of OTC drug products.

What labeling is required for prescription drug products and/or insulin? 21 C.F.R. Part 201 Subpart B addresses labeling requirements for prescription drugs products/insulin that may be displayed on immediate container or written, printed or graphic material accompanying an article. Sections 201.56 and 201.57 state the content and format requirements of labeling for human prescription drug and biological products which pertains to these labeling requirements.

What labeling is required for OTC drug products? 21 C.F.R. Part 201 Subpart C addresses labeling requirements for OTC drug products to be displayed on the immediate container or on written, printed, or graphic material accompanying an article. A complete rendering of the format and content requirements for OTC drug product labeling can be found in 21 C.F.R. § 201.66; an abbreviated list of relevant requirements is provided below. 21 CFR Section 201.66 (d) states—

> *The outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper, shall contain the title, headings, subheadings, and information set forth in* paragraphs (c)(1) *through (c)(8) of this section, and may contain the information under the heading in paragraph (c)(9) of this section, in the order listed.*
>
> i. *(Title) "Drug Facts".*
> ii. *"Active ingredient" or "Active ingredients"*
> iii. *"Purpose" or "Purposes"*
> iv. *"Use" or "Uses"*
> v. *"Warning" or "Warnings"*
> vi. *"Directions"*
> vii. *"Other information"*
> viii. *"Inactive ingredients"*
> ix. *"Questions?" or "Questions or comments?"*

And,

> *In the interest of uniformity of presentation, FDA strongly recommends that the Drug Facts labeling be presented using the graphic specifications set forth in appendix A to part 201.*

Appendix A to 21 C.F.R. Part 201 includes graphic specifications strongly recommended by the FDA regarding Drug Facts labeling.

1-B. Considerations with regards to 38 M.R.S. § 1612 "Drug take-back stewardship program"

Maine's Drug take-back program requires that manufacturers collect unused "covered drugs" from Maine residents for safe disposal. It defines **covered drug** as follows:

> *"Covered drug" means any substance recognized as a drug under 21 United States Code, Section 321(g)(1), as amended, and any regulations adopted pursuant to that provision, that is sold, offered for sale or dispensed in the State, whether directly or through a wholesaler, in any form, including, but not limited to, prescription and nonprescription drugs, drugs in medical devices and combination products, brand and generic drugs and drugs for veterinary use.*
>
> *"Covered drug" does not include:*
>
> *(1) Vitamins or supplements;*
> *(2) Herbal-based remedies and homeopathic drugs, products or remedies;*
> *(3) Cosmetics, soap with or without germicidal agents, laundry detergent, bleach, household cleaning products, shampoo, sunscreen, toothpaste, lip balm, antiperspirant or other personal care products that are regulated as both cosmetics and nonprescription drugs under the Federal Food, Drug, and Cosmetic Act;*
> *(4) Pet pesticide products contained in pet collars, powders, shampoos, topical applications or other forms and prescription pet food;*
> *(5) Drugs that are biological products, as defined in 21 Code of Federal Regulations, Section 600.3(h), if the manufacturer provides a program to take back that drug;*
> *(6) Drugs for which a manufacturer provides a program to take back those drugs as part of a United States Department of Health and Human Services, Food and Drug Administration managed risk evaluation and mitigation strategy;*
> *(7) Emptied syringes or emptied medical devices or the component parts or accessories of those products or devices;*
> *(8) Drugs that are used solely in a clinical setting; and*
> *(9) Dialysate drugs required to perform home kidney dialysis.*

While the law requires the Producer Responsibility Organization to provide *"a description of how separation of those covered drugs from packaging by consumers will be encouraged to reduce transportation and disposal costs",* packaging of unused covered drugs that is returned with those drugs will be collected and disposed of through the program. The alternative collection plan outlined in section 8 of 38 MRS 2146 is intended to compensate

producers for packaging they collect and recycle when operating an approved collection program. Note, federal law prohibits review of the material collected through a drug take-back program. Therefore, packaging collected through this program cannot be measured or separated for the purpose of recycling.

2-A. Material that is used for the containment, protection, delivery, presentation or distribution of a medical device

How is medical device defined? 21 U.S.C. § 321(h)(1) of the FFDCA **defines device as**—

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part, or accessory which is—

1. *recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,*
2. *intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or*
3. *intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and*
4. *which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.*

Some examples. For a complete list of medical devices, reference 21 C.F.R. parts 800-898.

- In vitro diagnostics (IVD), such as pregnancy/toxicology/genomic tests, reagents, calibrators, and controls
- Clinical chemistry and clinical toxicology devices, such as sample collection devices, assays, analyzers, benchtop test systems, and medical use lab equipment
- Hematology and pathology devices, such as microscopes, reagents, processing equipment, centrifuges, calibrators, and blood bank supplies
- Immunology and microbiology devices, such as microscope slides and PCR supplies
- Anesthesiology devices, such as gas analyzers, computers, monitors, plethysmographs, and pressure meters
- Cardiovascular devices, such as pacemakers, stents, grafts, catheters, and heart valves
- Dental devices, such as plates, scalers, drills, implants, floss, toothbrushes, and teething rings
- Ear, nose, and throat devices, such as hearing aids, tubes, dilators, balloons, scopes, splints, and lasers

- Gastroenterology-urology devices, such as enemas, retractors, evacuators, ligatures, dislodges, and lithotripters
- General and plastic surgery devices, such as prostheses, adhesives, surgical mesh, wound dressings, surgical apparel, sutures, gloves, epilators, and tourniquets
- General hospital and personal use devices, such as thermometers, scales, manometers, sterilant, disinfectants, respirators, lifts, and incubators
- Neurological devices, such as clamps, clips, cuffs, stimulators, plates, probes, and electrodes
- Obstetrical and gynecological devices, such as aspirators, insufflators, condoms, breast pumps, tampons, and douches
- Ophthalmic devices, such as scopes, prisms, projectors, illuminators, lenses, spectacles, and sunglasses
- Orthopedic devices, such as prostheses, dynamometers, goniometers, cements, casts, and calipers
- Physical medicine device, such as canes, mechanical chairs, floatation cushions, crutches, arm slings, wheelchairs, heating pads, cold packs, and exercise equipment
- Radiology devices, such as cameras, scanners, phantoms, imaging systems, film, synchronizers, digitizers, analyzers, and protective shields

Note, the packaging material of some medical devices listed above does not leave the point of sale with the consumer and does not fall under the Packaging Stewardship Law's definition of packaging material.

What are the FDA packaging requirements for medical devices? 21 C.F.R. Part 820 Subpart K Section 820.130 states the requirements for device packaging—

> *Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.*

Some classes of medical devices have specific packaging requirements that may affect the recyclability or amount of packaging. For example, 21 C.F.R. § 800.10 states the following:

> *Eye cups, eye droppers, and other dispensers intended for ophthalmic use should be sterile, and may be regarded as falling below their professed standard of purity or quality if they are not sterile. These articles, which are regulated as medical devices unless packaged with the drugs with which they are to be used, should be packaged so as to maintain sterility until the package is opened and be labeled, on or within the retail package, so as to afford adequate directions and necessary warnings to minimize the hazard of injury resulting from contamination during use.*

The Department is seeking additional information on the extent to which these requirements affect the amount and/or recyclability of packaging for specific classes of medical

devices. Should a regulation specific to a class of medical devices affects the amount and/or recyclability of packaging, please bring it to our attention.

What must be included in labeling for medical devices? As noted above, 21 USC § 352 outlines labeling requirements for medical devices and states—

> *A drug or device shall be deemed to be misbranded- […]*
>
> > *(b) Package form; contents of label*
> > *If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.*

During review, the Department did not identify other labeling contents that need to appear on the label of the package for medical devices.

2-B. Material that is used for the containment, protection, delivery, presentation or distribution of a biological product

How is biological product defined? 21 C.F.R. § 600.3(h) defines biological product as—

> *A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.*

Some examples.

- Preventative and therapeutic vaccines
- Blood: whole, derivatives, and/or components
- Proteins (except chemically synthesized polypeptides), such as aprotinin
- Toxins and antitoxins, such as Botox
- Insulin and insulin analogs
- Human tissues
- Cellular therapies
- Gene therapies
- Monoclonal antibody therapies
- Hormone therapies
- Allergenic extracts
- Enzymes

Note, the packaging of biological products that does not leave the point of sale with the consumer does not fall under the Packaging Stewardship Law's definition of packaging material. However, when the packaging material of biological products do leave the point of sale with the consumer, according to 21 C.F.R. § 600.11(h), the following applies to containers and closures:

> *All final containers and closures shall be made of material that will not hasten the deterioration of the product or otherwise render it less suitable for the intended use.*
>
> And,
>
> *[…] final containers for products intended for use by injection shall be colorless and sufficiently transparent to permit visual examination of the contents under normal light.*

The Department is seeking additional information on the extent to which these requirements affect the amount and/or recyclability of packaging material for biological products that fall within the scope of the Packaging Stewardship Law's definition of packaging material. Should a regulation affect the amount and/or recyclability of packaging material of a biological product, please bring it to our attention.

3. Material that is used for the containment, protection, delivery, presentation or distribution of an over-the-counter human drug product for which tamper-evident packaging is required

What products require tamper-evident packaging? Tamper-evident packaging is required for all OTC drug products sold at retail except dermatological products, pastes and powders for teeth cleaning, insulin, and lozenges. A list of examples of OTC drug products is provided at the beginning of this document.

What is tamper-evident packaging? 21 C.F.R. § 211.132 defines a tamper-evident package as—

> *one having one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. […] A tamper-evident package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-evident feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.*
>
> **Some examples.**
>
> - Tape
> - Blister packs
> - Lidding films
> - Shrink bands
> - Over wrap

- Resealable stand-up pouches with tear away lids
- Induction seals

The Department is seeking additional information on the extent to which these requirements affect the amount and/or recyclability of packaging material for OTC drug products requiring tamper-evident packaging.

4. Material that is used for the containment, protection, delivery, presentation or distribution of a substance for which special packaging is required

How is special packaging defined? Per 16 C.F.R. Part 1700, **special packaging, or child-resistant (CR) packaging, is defined** as—

> *packaging that is designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.*

What products require special packaging? Certain products and products containing specific formulations of certain substances require special packaging. The Department has provided an abbreviated list of those products and substances below; for a complete description of products and formulations regulated see 21 C.F.R. § 1700.14.

- Aspirin and products containing aspirin
- Furniture polish
- Products containing methyl salicylate, such as rubs, ointments, powder, creams for aches and pains
- Controlled drugs, i.e., substances covered by the Comprehensive Drug Abuse Prevention and Control Act of 1970
- Products containing sodium and/or potassium hydroxide
- Kindling and/or illuminating preparations, such as cigarette lighter fluid, charcoal lighter fluid, camping equipment fuel, torch fuel, and fuel for decorative or functional lanterns
- Turpentine and products containing turpentine
- Liquid forms of methyl alcohol or methanol
- Products containing sulfuric acid
- Prescription drugs
- Products containing ethylene glycol, such as antifreeze
- Iron-containing drugs
- Dietary supplements containing iron
- Solvents for paint or other similar surface-coating material, such as thinners, removers, and brush cleaners
- Products containing acetaminophen
- Products containing diphenhydramine, such as antihistamines
- Glue removers containing acetonitrile

- Permanent wave neutralizers containing sodium bromate or potassium bromate
- Products containing ibuprofen
- Products containing loperamide, such as antidiarrheal and antiperistaltic agents
- Mouthwash with 3g or more of ethanol in a single package
- Lidocaine jelly
- Products containing dibucaine, such as hemorrhoidal ointments
- Naproxen or products containing naproxen
- Ketoprofen or products containing ketoprofen
- Products containing fluoride
- Products containing minoxidil, such as hair regrowth products
- Products containing methylacrylic acid
- Over-the-counter drug products that contain an active ingredient that was previously available for oral administration only by prescription
- Hazardous substances containing low-viscosity hydrocarbons
- Drugs and cosmetics containing low-viscosity hydrocarbons
- Products containing imidazolines, such as decongestants

What must be included in labeling for products requiring special packaging?

Manufacturers and packers of products subject to special packaging requirements are authorized to package products in noncomplying packaging that are conspicuously labeled to indicate they should not be used in households where young children are present. According to the noncomplying package requirements in section 1700.5, the labeling statement, "This Package for Households Without Young Children", shall appear conspicuously. If the area of the package is too small to accommodate the labeling statement mentioned above, a substitute statement, "Package Not Child-Resistant", complying with all requirements for size, placement, and conspicuousness, may be used.

The Department is seeking additional information on the extent to which these requirements affect the amount and/or recyclability of packaging material for products subject to special packaging requirements.