

however, because it may kill some sperm, it should not be used if pregnancy is desired." FDA considers claims related to relief of discomfort and claims related to the comfort and ease of sexual activity to be drug claims as they relate to the mitigation or treatment of disease (section 201(g)(1)(B) of the act) or use of a product to affect the structure or function of the body (section 201(g)(1)(C) of the act).

Some of these lubricant products also have claims such as: "For [or eases] insertion of rectal thermometers, enemas, douches, and similar types of nozzles, [and tampons and condoms]" and "widely used in gynecological and hospital procedures." Such claims make these products medical devices, and FDA has regulated them as such since 1976. FDA regulations in 21 CFR part 880 subpart G list products that are general hospital and personal use miscellaneous devices. The regulation in 21 CFR 880.6375 entitled "patient lubricant" states: "A patient lubricant is a device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device." Claims related to insertion of or facilitating use of rectal thermometers, enemas, douches, tampons, and condoms are considered device claims and are not included as part of this call for data. As these products with device claims can also have drug claims as discussed previously, FDA invites the submission of data to support the drug claims as part of this call for data.

Products marketed as a vaginal moisturizer have claims such as "replenishes your natural moisture for days at a time," "with regular use, provides continuous vaginal moisture for most women," and "safe immediate relief of vaginal dryness." FDA also considers these to be drug claims because they discuss affecting the structure or function of the body and, in some cases, may relate to the mitigation of a disease. Thus, they are also part of this call for data. FDA does not consider these uses of lubricants or vaginal moisturizers to be cosmetic claims because they do not relate to "cleansing, beautifying, promoting attractiveness, or altering the appearance" (see section 201(i) of the act).

G. Categories of Unreviewed Drug Products and Ingredients

The categories of unreviewed drug products listed in the following paragraphs are included in this call for data. The ingredients listed under each category heading are those that FDA has identified as possibly being in these products. This list is not intended to be

all-inclusive. Manufacturers of drug products in categories not previously reviewed or that contain ingredients not listed herein should submit appropriate information to FDA.

Ammonia as a reflex stimulant

Ammonia inhalants, aromatic spirits of ammonia

Bed-wetting deterrents

Belladonna

Blemish remedies (excluding topical acne active ingredients in 21 CFR 310.545(a)(1) and 333.310)

Allantoin, aloe vera gel, calamine, ethyl alcohol, eugenol, menthol, oil of eucalyptus, oil of peppermint, propylene glycol, sodium alkylaryl polyether sulfonate, titanium dioxide, triclocarban, triclosan

Breast creams (for use when nursing)

Cetyl alcohol, cocoa butter, cod liver oil, dimethicone, glycerin, glyceryl monostearate, hard fat, lanolin, mineral oil, petrolatum, white petrolatum

Bunion remedies

Drawing salves (excluding products labeled for the treatment of boils in 21 CFR 310.531) —includes products labeled for the drawing or removal of splinters, slivers, or similar items

Ergot fluid extract, ichthammol, juniper tar (oil of cade), magnesium sulfate, pine tar, rosin, rosin cerate, sulfur

Foot balms, baths, and creams (excluding topical antifungal active ingredients in 21 CFR 310.545(a)(22) and 333.210) —including claims for relieving foot muscle strains and soreness from working out

Amyl salicylate, benzalkonium chloride, benzocaine, cajeput oil, carbolic acid, di-isobutyl phenoxy ethoxy ethyldimethyl benzyl ammonium chloride, essential oils, formalin, glyceryl monostearate, 8-hydroxyquinoline, iodized botanical oil, iron sulfate, isopropyl alcohol, lanolin, lithium chloride, magnesium sulfate, methyl salicylate, natural pine needle oil, o-benzyl-p-chlorophenol, oil of eucalyptus, oil of peppermint, oil of thyme, potassium iodide, propylene glycol, sodium bicarbonate, sodium chloride, sodium hypochloride, sodium lauryl sulfate, sodium sesquicarbonate, sodium sulfate, talc, tragacanth mucilage, trisodium phosphate, water soluble chlorophyllins, witch hazel, zinc oxide

Impotency cures

Yohimbine, yohimbine hydrochloride

Impregnated body wraps for weight reduction

Amino acids, collagen, magnesium sulfate

Lubricants and vaginal moisturizers

Benzoic acid, carbomer 934P, carbopol 940, chlorhexidine gluconate, glucono delta lactone, glycerin, hydrogenated palm oil glyceride, hydroxyethylcellulose, mineral oil, natrosol 250H, nonoxynol-9, polycarbophil, polysorbate 60, polyethylene glycol 300, polyquaternium, propylene glycol, sodium hydroxide, sorbic acid, sorbitol

Medicated bath preparations

Acetylated lanolin, alkyl aryl polyether alcohol, benzophenone-3, colloidal sulfur, cottonseed oil, di-isopropyl sebacate, drometrizole, iron sulfate, isopropyl myristate, isopropyl palmitate, isostearic acid, lanolin alcohols extract, lanolin oil, liquid petrolatum, lithium chloride, magnesium sulfate, mineral oil, natural and essential oils, nonoxynol-5, octoxynol-3, PEG-4 dilaurate, PEG-8 dioleate, PEG-40 sorbitan peroleate, PEG-200 dilaurate, Peru balsam, PPG-15, pine needle oil, potassium iodide, stearyl ether oleth-2, sodium bicarbonate, sodium carbonate, sodium chloride, sodium hyposulfate, sodium lauryl sulfate, sodium sesquicarbonate, sodium sulfate, tar distillate, vitamin E, water soluble chlorophyllins

Nasal moisturizers

Glycerin, buffered isotonic saline solution, buffer solution, isotonic saline solution, normal saline, sodium chloride, saline phosphate

Nonantimicrobial skin wound cleansers (previously listed as "Detergents")

Tincture of Green Soap, phenol sodium, poloxamer 188

Prickly heat products

Aluminum hydroxide gel, zinc carbonate, zinc oxide

Skin protectant blister guard

Beta-hydroxyquinolone, eugenol, pyroxylin solution

Urethral creams for males

Urinary acidifiers

Ammonium chloride, ascorbic acid

Urinary alkalinizers

Sodium bicarbonate

Urinary analgesics/antiseptics

Benzoic acid, methenamine, methylene blue, phenazopyridine, phenazopyridine HCl, salicylamide, sodium salicylate

Wet dressings (excluding astringent active ingredients in 21 CFR 310.545(a)(18)(ii) and 347.10)

Aloe vera, calcium polysulfide, calcium thiosulfate, oxyquinoline sulfate, sodium propionate

Wound wash saline

Sodium chloride solution, sterile sodium chloride solution

Wrinkle removers

Alpha hydroxy acids