

Classification of Products as Drugs and Devices & Additional Product Classification Issues: Guidance for Industry and FDA Staff

FINAL GUIDANCE

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**U.S. Department of Health and Human Services
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Office of Special Medical Programs
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Classification of Products as Drugs and Devices & Additional Product Classification Issues: Guidance for Industry and FDA Staff¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page of this guidance.

I. INTRODUCTION¹

FDA regularly receives questions from medical product sponsors concerning the classification of their products.² We believe that efficient, effective regulation is facilitated by providing guidance on issues frequently raised in relation to Requests for Designation (RFDs) and other classification activities. In addition, providing as much clarity and predictability as possible with respect to product classifications should enable informed planning for product development. Accordingly, we have prepared this guidance to make the Agency's current thinking concerning certain product classification issues more readily and widely available.

While issues have arisen relating to whether a product should be classified as a drug, device, biological product, or combination product, most of these issues have related to whether a product should be classified as either a drug or a device.³ Accordingly, this guidance focuses particularly on cases in which a product⁴ may be classified as a drug or device.⁵ This guidance also addresses additional issues relating to product classification, including how to obtain classification determinations from FDA for medical products.

This guidance is organized into two substantive sections.

¹ This guidance has been prepared by the Office of Combination Products in consultation with the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Drug Evaluation and Research.

² Please note that “classification” as used in this guidance refers to a product’s designation as a drug, device, biological product, or combination product. This is distinct from the use of the term “classification” in reference to the class (Class I, II, or III) of a device as described in section 513(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

³ This guidance addresses the definitions for the terms drug, device, and biological product in section III. The term “combination product” is defined in 21 CFR 3.2(e). For further information regarding the definition for the term combination product and the regulation of combination products, please visit the webpage for the Office of Combination Products at www.fda.gov/CombinationProducts/default.htm.

⁴ The guidance’s discussion of the classification of products is also relevant to classification of the constituent parts of a combination product.

⁵ This guidance focuses on classification of products for human use. Distinct considerations may apply in determining how to classify a product intended for use in animals.

Section II offers guidance on the RFD process for obtaining a formal determination of a product's classification.

Section III presents general concepts regarding FDA's decision-making process for classification determinations and addresses issues that may arise in determining whether products should be classified as drugs or devices.⁶

The Agency recommends that sponsors contact the Office of Combination Products (OCP) to confirm the classification of any products they may wish to market if the appropriate classification is unclear or in dispute. Section IV provides contact information for OCP and responses to frequently asked questions.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

II. WHAT IS THE PROCESS FOR OBTAINING A FORMAL CLASSIFICATION DETERMINATION FOR A PRODUCT?

If the classification of a product as a drug, device, biological product, or combination product is unclear or in dispute, a sponsor can submit an RFD to OCP in accordance with Part 3 of Title 21 of the Code of Federal Regulations (21 CFR Part 3) to obtain a formal classification determination for the product, as provided for under section 563 of the FD&C Act (21 USC 360bbb-2). Any RFD determined to be incomplete will be returned to the sponsor with a request for the missing information.⁷ 21 CFR 3.8(a). Once OCP determines the RFD is complete for filing, the Agency reviews the RFD.

The sponsor recommends a classification in the RFD, and should explain the basis for the recommendation. While the sponsor should justify why it believes the product meets the recommended classification, we generally consider both the information provided in the RFD and other information available to the Agency at that time in making our designation.

Generally, OCP will respond to the sponsor in writing within sixty days of the RFD filing, identifying the classification of the product as a drug, device, biological product, or

⁶ This section generally focuses on approaches for determining whether a product should be classified as a drug or a device, based on application of the statutory definitions for these terms under sections 201(g) and 201(h) of the FD&C Act (21 USC 321(g) and (h)), respectively. Please note that this document does not focus on the classification of products as biological products regulated under section 351(i) of the Public Health Service Act (PHS Act) (42 USC 262(i)). It also does not address under what circumstances certain human cells, tissues, or cellular or tissue-based products (HCT/Ps), as defined in 21 CFR Part 1271, are regulated solely under section 361 of the PHS Act. For guidance concerning HCT/Ps, please visit <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/>.

⁷ See 21 CFR 3.7 for content requirements for RFDs.

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combination product. If the Agency does not provide a written response within sixty days, the sponsor's recommendation respecting the classification of the product is considered to be the final determination. 21 USC 360bbb-2(b) and (c).

RFD determinations pertain only to the product as described in the designation letter, including its proposed use(s) or indication(s) for use. The Agency may modify a determination made under section 563 regarding the classification of a product or the component of FDA that will regulate the product either with the written consent of the sponsor or for public health reasons based on scientific evidence. 21 USC 360bbb-2(b) and (c).⁸

A new determination may be appropriate if there is a change in, for example, a proposed indication for use or in a component of the product, or if the sponsor or Agency becomes aware of additional information that reveals that the means by which the product achieves its primary intended purposes differ from what was originally described in the RFD. For example, if a sponsor wished to change the indication for a product and that new indication would be achieved through a different mechanism than the original indication, a different classification for the new indication might be appropriate.

Please contact OCP if you have questions regarding whether to submit an RFD, what information to provide, or issues to address in an RFD to ensure its completeness and clarity.⁹

III. WHAT DOES FDA CONSIDER IN DETERMINING WHETHER TO CLASSIFY A PRODUCT AS A DRUG OR DEVICE?

FDA's determination of whether to classify a product as a drug or device is based on statutory definitions, as set forth in sections 201(g) and 201(h) of the FD&C Act, respectively. We apply these definitions to products, relying on the scientific data that are available to FDA at the time of the classification determination concerning the product for its proposed use(s)/indication(s).¹⁰

⁸ The sponsor may request reconsideration of the decision if its classification recommendation is not adopted by the Agency. See 21 CFR 3.8, 10.75. If the sponsor develops or becomes aware of new information that may affect the product's classification, the sponsor may also submit a new RFD seeking a new determination.

⁹ More detailed information on the RFD process is provided in OCP's guidance *How to Write a Request for Designation (RFD)*, available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm>. A pre-RFD process is available if a sponsor wishes to obtain a preliminary, non-binding classification determination or to engage in preliminary classification discussions with the Agency before filing a formal RFD. The RFD and pre-RFD processes are also available to sponsors to clarify the Center assignment for medical products, though this issue is beyond the scope of this guidance. More information about the pre-RFD process is available at <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM534898.pdf>.

¹⁰ If a product type has been classified by regulation, FDA would generally classify the product (including as a constituent part of a combination product) in accordance with the regulation, if the product (or constituent part) falls within the scope of that regulation. If the Agency concludes that it may be appropriate to propose changing a classification established by regulation, FDA would initiate notice and comment rulemaking to do so.¹¹ The device definition also includes a second exclusionary clause stating that a device "is not dependent upon being metabolized for the achievement of its primary intended purposes." This clause has not been at issue frequently in classification determinations. Accordingly, we do not offer guidance on its construction here. If sponsors have questions regarding the Agency's interpretation of this clause, they may contact OCP.

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Medical product classification determinations often focus substantially on whether a product that meets the definition of drug also meets the statutory definition of device. This section presents the drug and device definitions and discusses how the Agency addresses certain issues that arise when determining whether a product should be classified as a drug or device.

A. Statutory Definitions

1. Drug

Section 201(g) of the FD&C Act (21 USC 321(g)) provides that the term "drug" means:

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). . . .

2. Device

Section 201(h) of the FD&C Act (21 USC 321(h)) provides that the term "device" means:

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 which is not dependent upon being metabolized for the achievement of its primary intended purposes.

B. Certain key provisions of the definition of device

Conceptually, all FDA-regulated medical products meet the definition of "drug" under section 201(g) of the FD&C Act, due to the broader scope of the drug definition. For a medical product also to meet the more restrictive device definition under section 201(h) of the FD&C Act, it must (i) be "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article," and (ii) "*not* achieve its primary intended purposes through *chemical action* within or on the body of man or other animals" and (iii) "*not [be]* dependent upon being *metabolized* for the achievement of its primary intended purposes" (emphasis added).

The sponsor presumably has the most complete information relevant to how its proposed product achieves its primary intended purpose(s). Sponsors seeking a classification determination should present all available data and other information potentially relevant to that determination (without regard to whether the data or information supports the sponsor's preferred outcome). For example, for a sponsor seeking to classify its proposed product as a device, those data should demonstrate that its product meets the definition of a device.

At the classification stage, sponsors would not be expected to have gathered sufficient data to demonstrate that their proposed product meets the applicable marketing authorization standard (e.g., data demonstrating effectiveness). Therefore, the focus of FDA's classification analysis is on how the product would be expected to achieve its primary intended purposes, assuming it is capable of achieving its primary intended purposes at all. FDA will use its best scientific judgment to evaluate all available information relevant to the classification determination, including information submitted by the sponsor or available in the literature.

The following discussion presents the Agency's current thinking on certain issues that arise with respect to the statutory definition of device.

1. “Similar or related article” in the definition of device

The first clause of the device definition provides that the term “means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or *other similar or related article . . .*” (emphasis added). The issue of whether a product may be considered a “similar or related article” under this clause can arise, for example, with regard to products in liquid, semi-liquid, gel, gas, or powder form. In some cases, such products are appropriately considered “similar or related articles,” and may be classified as devices, so long as they also satisfy the remainder of the device definition under section 201(h) of the FD&C Act, including the chemical action exclusion discussed in section III.B.3 below. This could be the case, for example, for gels or powders put on the skin as a barrier, gases used as space fillers, or liquids used to clean either surgical instruments or contact lenses.

2. “Primary intended purposes” in the definition of device

Most often, in determining whether a product meets the device definition, questions arise concerning the exclusionary clause of the definition, which provides that a device is a product “which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals . . .”¹¹ A product that has chemical action could be a device if it does not achieve its primary intended purposes through that chemical action.

¹¹ The device definition also includes a second exclusionary clause stating that a device “is not dependent upon being metabolized for the achievement of its primary intended purposes.” This clause has not been at issue frequently in classification determinations. Accordingly, we do not offer guidance on its construction here. If sponsors have questions regarding the Agency's interpretation of this clause, they may contact OCP.

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For example, if the primary intended purpose of a hip joint replacement implant is to restore movement, and the implant also elicits a foreign body response through chemical action, that response would not be considered a primary intended purpose of the implant. Accordingly, such an implant could be classified as a device despite the chemical action, because such action does not achieve the product’s primary intended purpose. Similarly, if the primary intended purpose of an absorbable suture is to rejoin tissue, and the suture is also designed to be resorbed by the body through a combination of chemical action and metabolic activities, such resorption would not be considered a primary intended purpose of the product. Accordingly, such an absorbable suture could be classified as a device despite the chemical action and metabolic activity, because such action or activity does not achieve the product’s primary intended purpose.

3. “Chemical action” in the definition of device

FDA frequently receives questions from product sponsors concerning the Agency’s interpretation of the term “chemical action.” This term must be read in the context of the statutory definition of “device” as a whole. The determination of whether a product meets the device definition does not depend solely on whether the product exhibits “chemical action.” In particular, as explained in section III.B.2 and 4, a product that exhibits chemical action will still meet the device definition if the product “does not achieve its primary intended purposes through” that chemical action “within or on the body,” and otherwise satisfies the device definition.

Under the Agency’s interpretation of the device definition, a product exhibits “chemical action” if it interacts at the molecular level with bodily components (e.g., cells or tissues) to mediate (including promoting or inhibiting) a bodily response, or with foreign entities (e.g., organisms or chemicals) so as to alter that entity’s interaction with the body.¹² We note that this type of interaction is consistent with the term “pharmacological action” as that term is generally understood in the medical field. Accordingly, we have used “pharmacological action” as a short-hand throughout the rest of this guidance for ease of explication and recognition. The examples presented in section III.B.5 offer illustration of FDA’s interpretation of chemical action.

4. “Within or on the body” in the definition of device

Because a device “does not achieve its primary intended purposes through chemical action *within or on the body* of man or other animals” (emphasis added), a product can be a device even if it achieves its primary intended purposes through chemical action, so long as the chemical action does not occur “within or on the body” (and the product meets the other elements of the definition of device under section 201(h)).

Whether chemical action is occurring “within or on the body” is generally a straightforward matter. If the chemical action is occurring inside the body or on the surface of the body, it is within or on the body. For example, the chemical action of an orally ingested pill

¹² For purposes of this interpretation, an interaction at the molecular level occurs through either chemical reaction (i.e., formation or breaking of covalent or ionic bonds), intermolecular forces (e.g., electrostatic interactions), or both. The mere exchange of non-chemical energy (e.g., electromagnetic or thermal energy) between a product and the body would not constitute “chemical action.”

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or tablet of a decongestant would be “within the body,” and the chemical action of a spray or cream for treatment of dermatitis when applied to the skin would be “on the body.” Similarly, it is generally a straightforward matter to determine that chemical action is not occurring within or on the body. For example, the chemical action of an antimicrobial agent used to clean a surgical instrument before that instrument is used is not occurring within or on the body.

However, the Agency has on occasion considered some situations in which it may be less clear whether chemical action is occurring within or on the body. For example, we have determined that chemical action occurring solely within an extracorporeal device, specifically a kidney hemodialysis machine, is not occurring within or on the body. Similarly, we have determined that the chemical action of a transport solution to preserve a donor organ for transplantation while in an organ transport container is not occurring within or on the body.

5. Illustrative Examples

The following examples further illustrate the application of some of the key provisions of the device definition discussed above. Table 1 contains some examples of medical products that achieve their primary intended purposes through chemical action within or on the body. Table 2 contains some examples of medical products that do not achieve their primary intended purposes through chemical action within or on the body.

Table 1: Examples of Medical Products that Achieve Their Primary Intended Purposes through Chemical Action within or on the Body

Product	Description
Aspirin	Aspirin is used for pain relief. Acetylsalicylic acid (aspirin) contains an acetyl group that has the ability to covalently bind to a serine residue of a cyclooxygenase enzyme (COX-1 or COX-2). This is considered pharmacological action because it inactivates the enzyme and thereby inhibits the synthesis of prostaglandin and thromboxanes, which suppresses the body’s inflammatory response for pain relief.
Beta Blockers	Beta blockers are used to reduce blood pressure. Cells contain beta receptors that can be stimulated by neurotransmitters such as adrenaline/epinephrine. Beta blockers, like propranolol, bind beta receptors (b1 and b2) and exhibit pharmacological action by inhibiting the activation of the signaling cascade. This blockage causes cardiac cells to reduce the strength of cardiac contractions and heart rate.
Magnesium Sulfate	Magnesium sulfate is used as replacement therapy for magnesium deficiency. It acts as a catalyst in enzymatic reactions (a molecular-level interaction). While the chemical or atomic structure of magnesium sulfate is not altered, its participation in enzymatic reactions is considered a pharmacological action because it impacts various cellular and molecular processes.

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Polymyxin B Sulfate	Polymyxin B sulfate is an antibiotic that is used to treat bacterial infection. It is composed of a cationic protein surfactant that has fatty acid functional groups. Polymyxin B sulfate acts through intermolecular forces, by binding to components of the bacterial membrane (i.e., the membrane of the foreign entity) and by association/fusion of the fatty acid portion of the molecule with the lipid bilayer via hydrophobic interactions. This binding is a pharmacological action because it disrupts the integrity of the bacterial membrane, which causes organism death, thereby treating the bacterial infection.
Hydroxocobalamin	Hydroxocobalamin is used as an antidote to cyanide poisoning. The cobalt moiety of hydroxocobalamin exhibits pharmacological action because it chemically reacts with cyanide, a toxic chemical agent, to form cyanocobalamin, a non-toxic compound, and the ability of hydroxocobalamin to interact with cyanide facilitates the removal of the toxic agent in order to inhibit the toxic effects of cyanide on the body.

Table 2: Examples of Medical Products That Do Not Achieve Their Primary Intended Purposes through Chemical Action within or on the Body

Product	Description
Abdominal Adhesion Barrier	Inert, biodegradable synthetic polymers can be used to reduce post-operative adhesions with tissues and organs within the abdominal cavity. An implanted physical barrier sheet composed of such polymers would act to reduce adhesion through physical separation of tissue and not through pharmacological action on the surrounding tissue.
Polymethylmethacrylate (PMMA)	PMMA is an acrylate polymer that is used as a temporary bone spacer. PMMA is built from methyl methacrylate monomer units, which undergo free radical polymerization in the presence of an initiator compound. The molecules that are part of the polymerization process interact with each other to create a solid mass to fill a bone void physically. The process does not require an interaction between the PMMA and the bone at the molecular level and, therefore is not considered chemical action within or on the body.
Topical Surgical Adhesive	Cyanoacrylate is an acrylic resin that is used to approximate skin tissue as an adjunct to a wound closure product. The resin undergoes anionic polymerization in the presence of water. The chemical reaction that occurs between the resin and ions in the water allows it to form into long polymer chains. This type of adhesive can bond to a cut/incision, creating a physically-intact film to aid in keeping skin edges together. While the product binds to tissue, it does not exhibit pharmacological action because that binding does not mediate a bodily response.

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Gold Nanoparticles	Nanoparticles composed of gold can be used to treat cancer. When gold nanoparticles are injected into a tumor site and exposed to electromagnetic energy, they absorb the electromagnetic energy and convert it to thermal energy, and this heat is transferred to the surrounding cells or tissue. The heat transfer, as opposed to a binding interaction with the nanoparticle, causes the cancer cells to die. Therefore, this effect is not achieved through chemical action.
Cryosurgery for Wart Removal	Cryogen (liquid gas), such as nitrogen or dimethyl ether, is used to treat common and plantar warts. The liquid gas is extremely cold and freezes the wart, resulting in damage to the topmost layer of cells. A physiological effect (i.e., cell death) results from heat transfer, not from a binding interaction with the gas. Therefore, the freezing is not considered chemical action.
Dental Amalgam	A resin that fills a cavity in a tooth as part of the treatment of dental caries may bind to the tooth via covalent bonding, or rely in part on intermolecular forces to change from liquid or paste to solid form. However, this binding and/or state change does not mediate a bodily response, but rather produces a solid mass, to fill the cavity. Therefore, it would not be considered chemical action.
Respirator Mask with Antimicrobial Filter	An antimicrobial product impregnated into a filter on a respirator mask to kill microbes that the user might otherwise inhale would exhibit pharmacological action. However, while the mask is in contact with the user's face, the filter is not. So, the chemical action occurring on the filter is not occurring within or on the body.

C. How is a product classified if it meets the definition for drug (or for both drug and device) and also meets the definition for biological product?

As explained in section III.B, products that meet the device definition in 201(h) of the FD&C Act also meet the drug definition in 201(g) of the FD&C Act. In addition, products that meet the drug definition, or both the drug and device definitions, may also meet the definition of biological product under section 351(i) of the PHS Act (42 USC 262(i)).

Section 351(i) provides that:

The term “biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide),¹³ 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.

¹³ For guidance on FDA’s interpretation of the category “protein (except any chemically synthesized polypeptide)” see *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*, at Q.II.1 (April 2015), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444661.pdf>.

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Products that meet the drug definition and that also meet the definition of biological product are classified as biological products, and are generally subject to licensure under the PHS Act.¹⁴ Products that meet the definitions for drug, device, and biological product may also be classified as biological products. If you have questions regarding whether a product meets the definition of biological product or how this might affect its classification, please contact OCP.

IV. ADDITIONAL INFORMATION

For further information on the classification of products as devices, drugs, biological products, or combination products, please refer to the Frequently Asked Questions on the next page, OCP's webpage at <https://www.fda.gov/CombinationProducts/default.htm> or contact OCP at:

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¹⁴ Certain biological products have been historically approved under the FD&C Act and may continue to be subject to approval under the FD&C Act until March 23, 2020. See Section 7002(e) of the Biological Price Competition and Innovation Act of 2009; see also FDA, *Implementation of the “Deemed to be a License” Provision of the Biologics Price Competition and Innovation Act of 2009*, available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm490264.pdf>.

FREQUENTLY ASKED QUESTIONS

1. Can a product be classified as a device if it exhibits “chemical action”?

Yes, if the product does not achieve its primary intended purposes through chemical action within or on the body and otherwise meets the definition of a device. However, products that meet the device definition may be regulated as drugs or biological products in some cases. See question 2.

2. If a product meets the definition for drug at 21 USC 321(g) and for device at 21 USC 321(h), how is it classified?

Generally, the product would be classified as a device, unless it falls within a special category (for example, apparatuses used in the preparation of compounded positron emission tomography drugs are classified as drugs, see 21 USC 321(ii)).

3. Can the proposed use or indication of a product affect its classification?

Yes. Two products with exactly the same composition can be classified differently based on their primary intended purposes. For example, if a vaginal product is intended solely to facilitate ease and comfort during sexual intercourse and it achieves this through lubrication that decreases friction (via mechanical/physical action) and not through chemical action, it is classified as a device. However, the same product can be classified as a drug if it is intended, for instance, to alter pH, control odor, or prevent infection, and does so through chemical action as discussed in III.B.3 above.

4. What should you do if, after reviewing this guidance, you are unsure of how your product is classified?

You should contact the Office of Combination Products (Combination@FDA.GOV) for feedback. OCP will provide you feedback, including on whether a pre-RFD or an RFD may be appropriate and what information you should provide.

5. Where can you find additional information about product classification?

Additional information on classification is posted on OCP’s webpage at: (<https://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm>)

For additional information on how to submit an RFD, see *How to Write a Request for Designation (RFD)* (<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm>).

More information about the pre-RFD process is available at <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM534898.pdf>.