Brief Summary of the General and Plastic Surgery Devices Panel Meeting – September 20 and 21, 2016

Introduction:

The General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee to the Food and Drug Administration met on September 20 and 21, 2016 at the Gaithersburg Hilton, 620 Perry Parkway, to discuss and make recommendations regarding the classification of certain wound dressings combined with antimicrobials and other drugs as part of the routine process for device classification. FDA appreciates the importance of appropriately addressing the individual and societal risks of antimicrobial resistance (AMR) in light of the increasingly significant national public health concern posed by AMR. These products are regulated under product code FRO, ‘‘Dressing, Wound, Drug,’’ and are considered ‘‘pre-amendments’’ because they were in commercial distribution prior to May 28, 1976, when the Medical Devices Amendments were enacted, and have not yet been classified under section 513 of the Federal Food, Drug, and Cosmetic Act. As a part of the classification process, FDA sought committee input on the indications for use, risks to health, and safety and effectiveness of these wound dressings combined with drugs, and how they should be classified.

September 20, 2016 Panel Deliberations/FDA Questions:

On September 20, the discussion focused on the clinical use, guidelines, benefits, risks and evidence related to these products. FDA first outlined the historical and current regulation of these products, including the testing and evaluation currently provided in premarket submissions. Additionally, FDA outlined the clinical considerations for these products from premarket and postmarket perspectives, and reviewed the benefits and risks specifically for antimicrobial agents in wound dressings, in light of the individual and societal antimicrobial resistance concerns. A guest speaker, Finn Gottrup, M.D., DMSCi, provided a global perspective regarding the international challenges in the area of wound care.

During the afternoon deliberations, the advisory committee provided comment on a diverse range of issues. There was discussion about the clinical relevance of specific claims, including claims of reducing bioburden on the dressing itself. While not unanimous, some members of the committee did not believe there is clinical value in such a claim. The committee indicated that there would be a benefit to improved terminology and claims applied to wound dressings combined with antimicrobial agents. Additionally, the committee noted the diversity of wound types and patient conditions, and discussed how the indications may vary among or within the three subcategories of wound dressings combined with antimicrobial agents and drugs (solids; gels, creams, and ointments; and wound washes). As the committee discussed the types of evidence needed to support various claims, assessments involving patient reported outcomes, registries, and real world evidence were suggested as additional means for assessing these products as part of the overall care of a

patient with a wound. The Advisory Committee discussed the risks and potential mitigations posed by the inclusion of more than one antimicrobial in a single product, and how to assess effects in these situations, whether synergistic, additive, or antagonistic with respect to reduced bioburden, and possibly promotion of AMR. The committee recommended that the added benefit of additional agents be individually evaluated. The committee also noted that when assessing the benefit risk profile of a product, that higher risk may be tolerated when known benefit is high, whereas lower risk should be tolerated when known benefit is low or not established.

September 21, 2016 Panel Deliberations/FDA Questions:

On September 21, the panel discussed the classification of three subcategories of wound products combined with drugs: Solid Wound Dressings; Wound Dressings formulated as a Cream, Gel, or Ointment; and Liquid Wound Washes. The panel generally agreed that these subcategories were a reasonable method for grouping the products, with the exception of wound dressings serving as a covering for catheter insertion sites (which some members believed should be a separate group). Some panel members also recommended that wound dressings combined with drugs could be further subcategorized by indications and wound type such as acute versus chronic, infected versus non-infected, burns, catheter insertion sites, size of wound, and for pediatric use. There was also discussion regarding subdividing silver into subcategories.

For Solid Wound Dressings combined with Drugs: The panel reviewed the list of risks to health and potential mitigation measures provided by the FDA and agreed that the list was acceptable. Some panel members stated that an additional risk may be leaching, systemic absorption of the drug, inhibition of wound healing, and reduced tensile strength of the dressing due to added agents. Some members stated that bench testing could be a potential mitigation measure for the risk of retention of dressing material in the wound. In general, a majority of the panel recommended that Solid Wound Dressings combined with Drugs should be classified into Class II with special controls, with the exception of certain solid wound dressings combined with antimicrobial drugs such as antibiotics; two committee members, the patient and consumer representatives, believed all wound dressing combined with drugs should be classified as Class III because of the absence of high quality evidence of benefit; four committee members recommended Class III be considered for any product combined with an antibiotic or an antimicrobial which may indirectly contribute to antibiotic resistance.

For Wound Dressings combined with Drugs formulated as a Cream, Gel, or Ointment: The panel reviewed the list of risks to health and potential mitigation measures provided by the FDA and agreed that the list was acceptable. Some panel members stated that cumulative residual material in the wound could present an additional potential risk that could be mitigated by labeling. Some panel members also questioned the utility of the antimicrobial in a cream, gel or ointment beyond maintaining stability and/or sterility when there may be other means to reduce bioburden in the product. The committee believed all such claims should be supported by evidence. The risk of systemic absorption and topical toxicity was also of concern to the committee. In general, the majority of the panel recommended that Wound Dressings combined with Drugs formulated as a Cream, Gel, or Ointment should be classified into Class II with special controls, with the exception of certain wound dressings

formulated as a cream, gel, or ointment combined with antimicrobial drugs such as antibiotics (with similar consideration to agents that may select for resistance in indirect ways), for which some members of the committee recommended class III.

For Liquid Wound Washes combined with Drugs: The panel reviewed the list of risks to health and potential mitigation measures provided by the FDA and agreed that the list was acceptable. The panel discussed the clinical value of debridement and irrigation and questioned the value of added agents. There was agreement that agents in the wash would affect the wound directly and there was skepticism regarding whether these products should be combined with drugs at all. In general, the majority of the panel recommended that Liquid Wound Washes combined with Drugs should be classified into Class II with special controls or Class I, depending on the toxicity of the product, with the exception of certain liquid wound washes combined with antimicrobial drugs such as antibiotics (with similar consideration to agents that may select for resistance in indirect ways), for which some members of the committee recommended class III.

Contact: Evella Washington, Designated Federal Officer,
(301) 796-6683 Evella.washington@fda.hhs.gov
Transcripts may be purchased from: (written requests only)
Free State Reporting, Inc. 1378
Cape St. Claire Road Annapolis, MD 21409
410-974-0947 or 800-231-8973 Ext. 103
410-974-0297 fax
Or
Food and Drug Administration
Freedom of Information Staff (FOI)
5600 Fishers Lane, HFI-35
Rockville, MD 20851
(301) 827-6500 (voice), (301) 443-1726