



AFFORDABLE ACCESS

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CONFIDENTIAL

Re: Afaxys Inc. Drug Product MSDS Exemptions

Products: Aubra® (levonorgestrel and ethinyl estradiol tablets, USP 0.1mg/0.02mg)
NDC 50102-120-48

Chateal® (levonorgestrel and ethinyl estradiol tablets, USP 0.15mg/0.03mg)
NDC 50102-130-48

Lyza® (norethindrone tablets, USP 0.35mg)
NDC 50102-100-48

Tarina™ (norethindrone acetate and ethinyl estradiol tablets, USP and ferrous fumarate tablets)
NDC 50102-128-03

Exemption: The above referenced products are exempted under 19 CFR Section 1910.1200(b)(6)(viii) of the HCS requirements for an MSDS because each product is a FDA approved "drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies). Furthermore, Afaxys has determined that these pharmaceuticals are NOT hazardous to employees exposed under normal conditions of use or in a foreseeable emergency. There are shipped as tablets in PVC-foil blister, contained in unit of dispensing carton or pouch. Cartons/Pouches packed into multiunit packs, and final shipping cases.

Adverse Events, Medical Inquiry, Product Complaints: 1-855-888-2467



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