July, 2015

SDS NOT REQUIRED

Re: ANDA 090836 Cephalexin Capsules, USP 250mg, 500mg, 750mg

As stated in 29 CFR 191 0.1200(b) (6)(vii), any 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); and drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); are exempted from the requirement of an SDS. I write to claim an exception of SDS for the above referenced FDA approved drug product. Please note the approved package insert of the listed product does not recommend dissolution or any further action prior to administration to the patient.

On the basis of the foregoing, Ascend Laboratories, LLC submits that an SDS statement is not required for the listed product marketed under approved ANDA 090836 and, therefore, requests that it be categorically excluded from the requirement to submit SDS.

If you need any additional information, please contact me directly.

Sincerely,

Hindy Schiff

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