FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology

QUESTIONS TO ADVISORY COMMITTEE

JULY 22, 2008

Nanotechnology in Drug Manufacturing, Drug Delivery, and Drug Products

1. Is CDER guidance needed for the development of nanotechnology derived drug applications? (Yes/No/Abstain)
2. If guidance is needed from CDER, what areas should these guidances focus on?
3. In light of the many definitions of nanotechnology available, how should CDER define nanotechnology, for the purposes of guidance development?

Lead in Pharmaceutical Products

1. What additional information would be necessary for us to gather to appropriately determine the next steps?

JULY 23, 2008

Bioequivalence Methods for Locally Acting Drugs that Treat Gastrointestinal (GI) Conditions

1. What role should biorelevant dissolution play in developing BE recommendations for low solubility locally acting drugs that treat GI conditions?
2. What role should systemic pharmacokinetics play in developing BE recommendation for low solubility locally acting drugs that treat GI conditions?

Drug Classification of Orally Disintegrating Tablets (ODT)

1. What properties (*in-vivo* or *in-vitro*) do you consider critical to this dosage form?
2. Should physical properties (e.g., size, formulation, and disintegration times) be a primary factor in determining conformance to this dosage form? (Yes/No/Abstain)
    a. If so, how specific or restrictive should the criteria be?

3. Can labeling (i.e., instructions for use) be considered sufficient to define the dosage form? (Yes/No/Abstain)
    a. If so, should labeling describe/include differences between/among NDA and ANDA products?
4. What, if any, special issues should be considered (e.g., patient compliance, target populations/conditions)?