FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Nonprescription Drugs Advisory Committee (NDAC) Meeting
Hilton Washington DC North/Gaithersburg, The Ballrooms
620 Perry Pkwy., Gaithersburg, Maryland
April 15, 2016

DRAFT QUESTIONS

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1. **DISCUSSION**: Discuss the safety profile of adapalene gel 0.1% in the over-the-counter (OTC) setting. In your discussion, please consider the following:

    a. use by females with reproductive potential (i.e., teratogenic risk),

    b. pediatric use (i.e., use by adolescents and/or younger children), and

    c. potential for misuse (e.g., excessive use or use for non-acne conditions) and the consequences of such use.

2. **VOTE**: Has the safety of adapalene gel 0.1% for OTC use for the treatment of acne been adequately demonstrated?

    a. If not, what additional data, if any, should be obtained to demonstrate safety in the OTC setting?

3. **DISCUSSION**: Discuss the proposed Drug Facts Label and Consumer Information Leaflet.

    a. **DISCUSSION**: If your review of the label and leaflet identifies concerns, please discuss ways in which the documents could be revised to encourage the safe and proper use of the product by consumers.

4. **VOTE**: The sponsor proposes OTC use of adapalene gel 0.1% for the treatment of acne in consumers ages 12 years and older. Does the totality of the data support the use of this product OTC?

    a. If yes, do you have additional comments or recommendations for labeling?

    b. If not, what further data, if any, should be obtained to support such use?