**Joint Dental/ENT Device Advisory Panel Questions**

1. As noted in FDA's presentation, the following types of devices may be considered for, or have already been cleared for, over-the-counter (OTC) status for the indications of snoring and/or obstructive sleep apnea (OSA):

| Device | Snoring | Mild OSA | Moderate OSA | Severe OSA |
|---|---|---|---|---|
| Tongue Retaining Device | Rx | | | |
| Mandibular Repositioning Device | Rx | Rx | Rx | |
| Palatal Lifting Device | Rx | | | |
| Nasal Dilators | OTC | | | |
| Cervical Pillows | OTC | OTC | | |
| Mandibular Support Devices | | | | |

   Please discuss the risks and benefits of allowing devices to be marketed over-the-counter for the treatment of:

   a. snoring
   b. mild OSA
   c. moderate OSA
   d. severe OSA

   In particular, please discuss the overall risk/benefit ratio assessment as it relates to level of disease severity and discuss the potential risks related to delay in professional diagnosis and treatment resulting from OTC availability/use of these devices.

2. If, after your discussion of question #1, you believe that certain devices, *would* be appropriate for OTC treatment of OSA, please discuss the following:

   ?? how adequate product labeling can be written to assist the user in self-diagnosing and differentiating the severity of OSA he/she is experiencing to ensure proper use
   ?? any other general or specific labeling restrictions which you believe would be appropriate for OTC devices to treat snoring and /or OSA (e.g., any specific types of contraindications, warnings, or precautions which you believe should appear in the device labeling)

3. Please discuss the following aspects of the clinical data which may be appropriate to be included in marketing submissions for snoring and/or OSA:

   a. The general clinical study design including control group, if needed
   b. The endpoints which would be acceptable for the assessment of the effectiveness of treatment

c. The degree of improvement for each of the endpoints which would be clinically meaningful, assuming an acceptable adverse event profile
d. The specific adverse events, if any, which should be carefully assessed by FDA from the clinical trial
e. Whether any of the responses to 3a-3d would be different based on the severity of snoring and/or OSA (mild, moderate, severe).
f. Any specific considerations in trial design for OTC indications
g. Any specific device types or indications which would not require clinical data