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

Bone, Reproductive, and Urologic Drugs Advisory Committee (BRUDAC) Meeting
Tommy Douglas Conference Center, 10000 New Hampshire Ave, Silver Spring, MD
December 6, 2016

DRAFT QUESTIONS

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1. **DISCUSSION:** For drugs intended to treat secondary hypogonadism while preserving existing testicular function (e.g., maintenance of sperm parameters or demonstration of continued fertility), discuss:

    a. The patient population that should be enrolled in clinical trials
    b. How preservation of testicular function should be defined and assessed
    c. Acceptable endpoints for demonstrating clinical benefit for men with classic hypogonadism and for those who do not have classic hypogonadism
    d. Other trial design features that should be considered

2. **DISCUSSION:** For drugs intended to treat secondary hypogonadism while improving testicular function (e.g., improved sperm parameters or amelioration of infertility), discuss:

    a. The patient population that should be enrolled in clinical trials
    b. How improvement in testicular function should be defined and assessed
    c. Acceptable endpoints for demonstrating clinical benefit for men with classic hypogonadism and for those who do not have classic hypogonadism
    d. Other trial design features that should be considered

3. **VOTE:** For products intended to treat men with hypogonadism attributed to obesity, is raising serum testosterone concentrations into the normal range for young, healthy eugonadal men and preservation of spermatogenesis, as assessed by maintenance of sperm concentrations, sufficient for establishing evidence of clinical benefit?

    If you voted "no," describe what endpoints would be needed to provide sufficient evidence of clinical benefit for such products. If you voted "yes," specify how preservation of spermatogenesis should be defined based on sperm concentrations, and provide an explanation for your definition.

DRAFT QUESTIONS (cont.)

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4. **VOTE:** For products intended to treat men with classic secondary hypogonadism and azoospermia or oligospermia, is raising sperm concentration above a specific threshold sufficient evidence of clinical benefit?

    a. Yes, but only for azoospermia
    b. Yes, but only for oligospermia
    c. Yes, for azoospermia and oligospermia
    d. No

    Include rationale for your answer. If you voted "no," describe what endpoint(s) would be needed to provide sufficient evidence of clinical benefit for such products. If you voted "yes," (chose a, b, or c), specify the threshold for sperm concentration that should be exceeded to establish evidence of clinical benefit and explain why you selected that threshold.

5. **VOTE:** For products intended to treat men with secondary hypogonadism and azoospermia or oligospermia, but who do not have classic hypogonadism, is raising sperm concentration above a specific threshold sufficient evidence of clinical benefit?

    a. Yes, but only for azoospermia
    b. Yes, but only for oligospermia
    c. Yes, for azoospermia and oligospermia
    d. No

    Include rationale for your answer. If you voted "no," describe what endpoint(s) would be needed to provide sufficient evidence of clinical benefit for such products. If you voted "yes," (chose a, b, or c), specify the threshold for sperm concentrations that should be exceeded to establish evidence of clinical benefit and explain why you selected that threshold.