



July 13, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

**Re: Draft Guidance for Industry on Female Sexual Dysfunction:
Clinical Development of Drug Products for Treatment
Docket No. 00D-1278, 65 Fed. Reg. 31916 (5/19/2000)**

Dear Dockets Management:

Pfizer Inc. submits these comments on the *Draft Guidance for Industry on Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment*, published in the *Federal Register* on May 19, 2000.

SECTION I - INTRODUCTION:

No comments

SECTION II -- DEFINITION OF FEMALE SEXUAL DYSFUNCTION:

Recommend that the component of "dyspareunia" should be changed to "sexual pain, e.g., dyspareunia, vaginismus, etc" to reflect a more encompassing definition of this component

Suggest a general definition of "personal distress" be provided to alleviate confusion in this section and later in SECTION IV, which indicates personal distress "should be measured to ensure appropriate patient selection":

- The definition of "personal distress" should be:
 - an individual motivated to seek treatment

It is not clear if the use of "**subtypes**" in this section is synonymous to "**subgroup**" in SECTION III. The proposal is to endorse that subtype and subgroup are synonymous thus appropriately designating a subject presenting with multiple components to each component of FSD. This would reflect clinical presentation, as well as, appropriate statistical design of clinical trials.

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**SECTION III -- APPROPRIATE STUDY POPULATIONS FOR CLINICAL TRIALS
INTENDED TO DEMONSTRATE EFFICACY:**

Recommend the definition of hormone replacement therapy to be inclusive and to also reflect the use of androgen and estrogen/androgen containing products.

Recommend expansion of the list of potential study population subgroups to include "women who present with medical (e.g., diabetes mellitus, spinal cord injury, multiple sclerosis, etc) or drug-induced (e.g., stable and controlled use of concomitant medication for the treatment of depression, anxiety {i.e., SSRI}, etc.) female sexual dysfunction"

SECTION IV -- OTHER STUDY CONSIDERATIONS:

The study should be conducted in a scientific manner to determine the safety, efficacy and toleration of the compound. As such, the **duration** of a study should be **event driven** (e.g., "*x*" *number of events/period*) and not **calendar driven** (e.g., *6 months*). Safety requirements should reflect ICH guidances.

In general, the guidance document should encourage sponsors to ensure the appropriate level of data collection frequency but it should not recommend a specific time interval, "every 1 or 2 weeks."

**SECTION V -- USE OF SCALES, QUESTIONNAIRES AND OTHER INSTRUMENTS
DURING DRUG DEVELOPMENT:**

No comments

SECTION VI -- CLINICAL TRIAL ENDPOINTS:

There is a conflict in the guidance as reflected in this section which indicates "the primary endpoints be clinically meaningful and specifically related to the component(s) of FSD" (refer to SECTION II {e.g., sexual desire, sexual arousal, dyspareunia, difficulty or inability to achieve orgasm}). The suggested primary endpoints recommend "sexual events or encounters" over time are number/frequency of sexual intercourse or orgasm and do not encompass all components of FSD. We recommend that primary endpoints appropriately reflect the FSD components, for example, a primary endpoint that may clinically and specifically reflect the FSD component of "decrease sexual arousal" may be subjects' increase in subjective arousal that is satisfactory.

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Recommend that the women participating in the study determine the subjective assessment of the sexual event or outcome as either successful or satisfactory. Women are separate and unique individuals and could misinterpret the use of both successful and satisfactory.

Sincerely,

A handwritten signature in cursive script, appearing to read "Cheryl Fossum Graham".

Cheryl Fossum Graham, M.D.
Senior Vice President
Pfizer Global Research and Development
Worldwide Regulatory Affairs

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