



University of Medicine and Dentistry of New Jersey
Robert Wood Johnson Medical School

Department of Obstetrics, Gynecology and Reproductive Sciences
Phone: (732) 235-6622/6623
Fax: (732) 235-7349

Clinical Academic Building
125 Paterson Street
New Brunswick, New Jersey 08901-1977

July 12, 2000

Dockets Management Branch (HF A-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Guidance for Industry: Female Sexual Dysfunction

As a physician and researcher in this field, I am concerned about the limited position of these guidelines.

Lack of desire is one of the most common sexual problems in women that greatly affect both psychological wellness as well as interpersonal relationships. Sexual response should be measured as a multidimensional assessment of receptivity, (satisfaction with frequency of sexual contact, arousal, intensity), and desire (sexual fantasies/thoughts). This document does not reflect appropriate measurements of female sexual function.

The primary endpoint for this document is frequency of sexual activity, which results in orgasm. In my opinion, this is slanted towards a male oriented perspective, and a heterosexual perspective, and cannot be considered an adequate definition for female sexual activity. There is nothing indicative within this document that sexual activity without orgasm is significant, and meaningful.

The symptoms listed are mainly treated in women to improve their Quality of Life, not specifically to increase the frequency of sexual activity. Enhancing Quality of Life, increased desire accompanied by satisfaction with activity, rather than purely performance should be the definitive reason for treatment. Improvement in interest, motivation, pleasure, and satisfaction should be regarded as the most important goals for intervention. To properly assess the value of the treatment these responses need to be identified and measured.

In summary, I feel that these guidelines are narrowly focused and do not properly address the subject of homosexual and heterosexual female sexual function. To more globally and objectively assess this subject, these guidelines should be re-evaluated from a more female perspective.

Sincerely,



Gloria A. Bachman, M.D.

00D-1278

C8

FedEx USA Airbill

Tracking Number

3320607754509247 **Recipient's Copy****1 From**
Date 7/13/00Sender's Name Gloria A. Bachmann, M.D. Phone (922) 235-7633Company AINDNJ/CAB Dept./Floor/Suite/Room 0B/6YNAddress 125 PATERSON ST STE 3100City NEW BRUNSWICK State NJ Zip 08901**2** Your Internal Billing Reference Information 531071**3 To**
Recipient's Name Dockets Management Branch Phone (HF-A-305)Company Food and Drug Administration Dept./Floor/Suite/Room Room 1061Address 5630 Fisherslane
(To "HOLD" at FedEx location, print FedEx address here)City Rockville State MD Zip 20852**For HOLD at FedEx Location check here**
 Hold Weekday (Not available with FedEx First Overnight)
 Hold Saturday (Not available at all locations)**For Saturday Delivery check here**
 (Extra Charge. Not available to all locations)
 (Not available with FedEx First Overnight or FedEx Standard Overnight)**4a Express Package Service Packages under 150 lbs.** Delivery commitment may be later in some areas.
 FedEx Priority Overnight (Next business morning) FedEx Standard Overnight (Next business afternoon) FedEx 2Day* (Second business day) **NEX FedEx First Overnight** (Earliest next business morning delivery to select locations) (Higher rates apply) *FedEx Letter Rate not available. Minimum charge: One pound FedEx 2Day rate.**4b Express Freight Service Packages over 150 lbs.** Delivery commitment may be later in some areas.
 FedEx Overnight Freight (Next business-day service for any distance) FedEx 2Day Freight (Second business-day service for any distance) FedEx Express Saver Freight (Up to 3 business-day service based upon distance)
(Call for delivery schedule. See back for detailed descriptions of freight products.)**5 Packaging** FedEx Letter FedEx Pak FedEx Box FedEx Tube Other Pkg.
Declared value limit \$500.**6 Special Handling**
Does this shipment contain dangerous goods? Yes (As per attached Shipper's Declaration) Yes (Shipper's Declaration not required)
 Dry Ice (Dry Ice, 9, UN 1845 III, kg, 904) CA Cargo Aircraft Only
(Dangerous Goods Shipper's Declaration not required)**7 Payment**
Bill to: Sender (Account no. in section 1 will be billed) Recipient Third Party Credit Card Cash/Check
(Enter FedEx account no. or Credit Card no. below) Obtain Recipient FedEx Account No.

Total Packages _____ Total Weight _____ Total Declared Value* \$ _____ .00 Total Charges \$ _____

*When declaring a value higher than \$100 per shipment, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE AND LIMIT OF LIABILITY section for further information.

8 Release Signature

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.

Questions?
Call 1-800-Go-FedEx
(1-800-463-3339)

272

WCSL 1196
Rev. Date 5/96
PART #147856
©1994-96 FedEx
PRINTED IN U.S.A.