



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Office of Combination Products
15800 Crabbs Branch Way (HFG-3)
Suite 200
Rockville, MD 20855

September 22, 2003

Handwritten marks: a vertical line of four 'M' characters on the left, and several closing curly braces '}' on the right.

Re: Request for Designation
Rostam pH Tampon
Our file: RFD 2003.024
Dated: August 12, 2003
Received and Filed: August 12, 2003

Dear []

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for the Rostam pH Tampon (pH tampon), which you submitted on behalf of your client, Rostam, Ltd., on August 12, 2003. The Office of Combination Products (OCP) filed the RFD on August 12, 2003. We have determined that the product is a combination product, and we have assigned it to the Center for Devices and Radiological Health (CDRH) as the lead agency center for premarket review and regulation based on our determination of the product's primary mode of action (PMOA).

Description of the Product

According to the RFD, the pH tampon is a menstrual tampon, which incorporates [] as additives. The additives are []
[] The additives consist of []
[] of total formulation, per tampon. This formulation is []
[] As described, as the tampon absorbs the menstrual fluid, the []
[] within the tampon will serve to neutralize the tampon's pH; [] are also absorbed by the surrounding vaginal tissue.

The product is intended to absorb menstrual fluid, while maintaining the pH in the tampon. []

Product Classification: Combination Product

The menstrual tampon component of the pH tampon is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act). The component comprised of additives of this product does not meet the device definition because the of this product is primarily intended to perform a chemical action within the body by reducing, not only in the tampon but also in the surrounding vaginal tissue.¹ Accordingly, the component meets the definition of a drug found at 201(g)(1)(D).

We have determined that, because the product is comprised of both device (menstrual tampon) and drug components, it is a combination product within the meaning of section 503(g) of the Act and Title 21 of the Code of Federal Regulations (CFR)-section 3.2(e)(1). Therefore, in accordance with 21 CFR section 3.4, assignment of a lead Center to conduct the review of a combination product is based on the Agency's determination of the product's primary mode of action.

Assignment of Lead Center: CDRH

One action of the pH tampon is to absorb menstrual fluid. Another of its actions is the maintenance of the pH level of the tampon, which is intended

We have determined that the product's primary mode of action is attributable to the device component's function of absorption of menstrual fluid, while the play a secondary role in supporting the functioning of the device component by reducing the pH level of the tampon and surrounding vaginal tissue.

Accordingly, we are assigning the product to CDRH for premarket review and regulation under the medical device provisions of the Act. Assignment of this product to CDRH is also consistent with the guidance provided by the Intercenter Agreement between CDER and CDRH (Sections VII.A.2 and VIII.A.5). We have also made preliminary determinations about other regulatory requirements that will apply to your combination product. The combination product will be subject to the manufacturing (21 CFR 820) and adverse event reporting requirements (21 CFR 803) applicable to medical devices. We encourage you to discuss with CDRH these and other regulatory requirements applicable to your combination product.

CDRH's Division of Reproductive, Abdominal, and Radiological Devices will have lead responsibility for the combination product's premarket review and regulation. CDRH will consult with CDER as appropriate regarding the drug component of your combination product. For further information about review requirements, please contact Mr. Colin Pollard, Chief, Obstetrics and Gynecology Devices Branch, at 301-594-1180. Please include a copy of this letter with your initial submission to CDRH.

¹ The RFD maintains that the primary intended purposes of this product are to absorb menstrual fluid, while and that any reduction of pH in the surrounding vaginal tissue is minor and unintended. In any event, one of the product's primary purposes is achieved through chemical action in the body by acting intended to act FDA considers articles, to be drugs.

Re: Rostam Ltd.
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You may request reconsideration of the classification or assignment of your product within 15 days of receipt of this letter. If you wish to request reconsideration, or for any other questions about this letter, please contact me at (301) 827-9229. Finally, the Office of Combination Products is available to you as a resource for questions or issues that may arise throughout the development of your product. You may reach us at the above address or by email at combination@fda.gov.

Sincerely,

A handwritten signature in black ink that reads "Leigh Hayes". The signature is written in a cursive, flowing style.

Leigh Hayes
Product Assignment Officer

Cc: Colin Pollard