DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2003

Armand Lione, PhD, President
Associated Pharmacologists and Toxicologists
533 4th Street, SE
Washington, DC 20003-4222

03P0166 – Citizen Petition on Menstrual Cups & Endometriosis
Dated: April 16, 2003
Received: April 17, 2003

Dear Dr. Lione:

The purpose of this letter is to respond to your above-referenced Citizen Petition on menstrual cups. Specifically, your petition asks the Food and Drug Administration (FDA) to "...revoke the approval for the marketing of the devices ... because there is a high [like]lihood that the use of these devices as directed will endanger a woman's reproductive health by inducing endometriosis."

In support of your petition, you state that manufacturers of menstrual cups were not required to submit clinical data demonstrating safety and efficacy of their devices. It is true that products FDA clears through the pre-market notification process do not ordinarily contain cleared data. Menstrual cups are pre-amendments medical devices, which means they were on the market before the Medical Device Amendments were enacted in 1976. Upon the recommendation of the Obstetrics and Gynecology Device Classification Panel, an FDA advisory committee, the agency classified menstrual cups in 1980 into Class II because we believed that intermediate level of regulatory controls would provide sufficient assurance of safety and effectiveness of this type of device. (I have enclosed the proposed and final rules on the classification of menstrual cups, including a summary of the classification panel recommendation). Because it is a Class II preamendments device, manufacturers may introduce menstrual cups to the market in the U.S. following FDA's clearance of a 510(k) premarket notification. Premarket notifications typically do not contain results from clinical studies. These submissions do contain information to demonstrate that the device is as safe and effective as a similar product that is already legally on the market. Data in 510 (k) submissions for menstrual cups ordinarily include descriptive and design information, performance characteristics, biomaterial safety information, and labeling.

While we agree that endometriosis is an important women's health issue, FDA does not believe that there are sufficient grounds to "withdraw the approval "of these devices, as you request.

We agree with the assertion in your petition that it is *physiologically plausible* that use (and misuse) of the menstrual cup might increase the risk of endometriosis by creating an obstruction

to the flow of menstrual effluent (blood and cells) out of the uterus, re-directing menstrual effluent into the peritoneal cavity via the fallopian tubes (retrograde menstruation). However, you have not submitted and we have not identified sufficient evidence to show this is more than theoretical.

To determine whether there might be other data available to support the Citizen Petition (besides what you included), we searched our MAUDE database for reports of adverse events associated with the use of a menstrual cup. Our search identified a total of sixteen reports. Only one report suggests a possible association between a menstrual cup and endometriosis (and adenomyosis). This is the same report you cite in your Citizen Petition.

We also performed a literature search on this topic and identified one case report of endometriosis and adenomyosis where use of a menstrual cup is listed as a potential cause (Gynecol Obstet Invest 706, Spechler et al, in press). Again, this case report appears to be the same case that appears in FDA's MAUDE database. Regarding the menstrual cup and other menstrual collecting devices, the abstract for this case report states that such devices may *theoretically* increase the likelihood of developing endometriosis or adenomyosis. This single case report does not constitute an adequate basis for FDA to issue an order to stop distribution of this product or withdraw approval. Additional information might warrant a review of menstrual cup labeling to determine whether an additional precaution or warning is needed, as well as whether menstrual cup wear time should be re-examined. However, in the absence of results from a well-designed clinical study, it would be inappropriate to make any statements about whether menstrual cups (or *other* menstrual fluid collecting devices) increase the risk of either endometriosis or adenomyosis.

If you have any questions regarding this letter, you may contact Mr. Colin Pollard, Chief of the Obstetrics and Gynecology Devices Branch, at (301) 594-1180.

Sincerely yours,

Linda S. Kahan

Linda S. Kahan,
Deputy Director
Center for Devices and Radiological Health

Attachments

cc: HFZ-215 (B. Noland, J. Sheehan)
HFZ-404 (POS, H. Rosecrans)
HFZ-470 (M. Byrne, J. Corrado, C. Pollard)
HFA-305

Draft: M. Byrne, C. Pollard – 9/16/03
Revised: L. Kahan 10-24-03

Classification and Premarket Notification

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (the act), as amended by the 1976 amendments (Public Law 94-295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), and The User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under Section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA classified menstrual cups in class II under these procedures.

A premarket notification (510(k)) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims. A legally marketed device is a device that was legally marketed prior to May 28, 1976 (preamendments device), or a device which has been reclassified from Class III to Class II or I, a device which has been found to be substantially equivalent to such a device through the 510(k) process, or one established through Evaluation of Automatic Class III Definition. The legally marketed device(s) to which equivalence is drawn is known as the "predicate" device(s).

Applicants must submit descriptive data and, when necessary, performance data to establish that their device is SE to a predicate device. Again, the data in a 510(k) is to show comparability, that is, substantial equivalency (SE) of a new device to a predicate device. Therefore, an applicant must submit clinical data in a 510(k) only when it is necessary to determine whether a device is substantially equivalent to a predicate device.

Withdrawal of Approval of Menstrual Cups

You request in your petition that FDA "withdraw the approval" of menstrual cups because manufacturers of the presently marketed menstrual cups have not submitted clinical data to demonstrate their safety and effectiveness. As discussed above, menstrual cups are marketed through the premarket notification process which only requires the applicant to demonstrate

substantial equivalence to other legally marketed devices. Therefore, FDA cannot withdraw the approval of these devices as such. FDA could remove these devices from the market through a cease distribution and notification order under section 518(e) of the act or by banning them under section 516 of the act.

Cease Distribution and Notification Order. Section 518(e) of the act (21 U.S.C. 360(h)(e)) provides that, if FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the agency may issue a cease distribution and notification order requiring the person named in the order to immediately:

(1) Cease distribution of the device;
(2) Notify health professionals and device user facilities of the order; and
(3) Instruct these professionals and device user facilities to cease use of the device.

Banning. The criteria for banning a device are set out in section 516 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360f) as follows:

SEC. 516. [360f] (a) Whenever the Secretary finds, on the basis of all available data and information, that -

> (a) (1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and
> (2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period; he may initiate a proceeding to promulgate a regulation to make such device a banned device.

In the regulations implementing section 516, FDA states that, in determining whether the risk of illness or injury is substantial, FDA will consider whether the risk is important, material, or significant in relation to the benefit to the public health from the continued marketing of the device (21 CFR 895.21(a)(1)).

Malfunction of the device could result in electrical shock to the patient. (c) Adverse tissue reaction: Material in the device could cause a systemic or local tissue reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that perineal heaters be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–548 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5390 as follows:

§ 884.5390 Perineal heater.

(a) *Identification.* A perineal heater is a device designed to apply heat directly by contact, or indirectly from a radiant source, to the surface of the perineum (the area between the vulva and the anus) and is used to soothe or to help heal the perineum after an episiotomy (incision of the vulvar orifice for obstetrical purposes).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N–1167]

[FR Doc. 79-9470 Filed 4-2-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 884]

Classification of Menstrual Cups

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying menstrual cups into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of menstrual cups:

1. Identification: A menstrual cup is a receptacle placed in the vagina to collect menstrual flow.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary for reasons for recommendation: The Panel recommends that menstrual cups be classified into class II (performance standards) because the Panel believes that the device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel believes that standards are necessary to assure that the device is readily cleanable to prevent the introduction of microorganisms which could cause infection. The Panel also believes that material standards are necessary to assure an adequate surface finish to prevent trauma. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on personal knowledge of and clinical experience with, menstrual cups.

5. Risks to health. (a) Infection: If the device is not properly cleaned, it may introduce microorganisms that could cause infection. (b) Trauma, hemorrhage, perforation: Failure of the support structure of the device could result in injury to the patient. (c) Adverse tissue reaction: Material in the device could cause a local tissue or systemic reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that menstrual cups be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–548 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5400 as follows:

§ 884.5400 Menstrual cup.

(a) *Identification.* A menstrual cup is a receptacle placed in the vagina to collect menstrual flow.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may

submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N-1168]

[FR Doc. 79-9471 Filed 4-2-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 884]

Classification of Scented Deodorized Menstrual Pads

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying scented deodorized menstrual pads into class II (performance standards). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classifeed into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Obstetrical and Gynecological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of scented deodorized mentrual pads:

1. Identification: A scented deodorized menstrual pad is an absorbent cotton or synthetic material pad with fragrant chemicals added for the purpose of deodorizing or for esthetic purposes. The device is used to absorb menstrual or other vaginal discharge. This generic type of device does not include devices with added drugs or antimicrobial agents.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that scented deodorized menstrual pads be classified into class II (performance standards) because the Panel believes that the device materials contacting the body should meet a biocompatibility standard to prevent an adverse tissue reaction. The Panel believes that general controls alone will not provide sufficient control over this characteristic. The Panel also recommends that the caution, "Discontinue use of sensitivity or irritation occurs" be stated in the device labeling and be prominently displayed on the front of the package. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on clinical experience with these pads. The Panel reviewed the complaint file of the only manufacturer of this device at the time of its meeting (November 23, 1976). The complaints dealt with irritation associated with the cosmetic used for deodorizing.

5. Risks to health: Adverse tissue reaction: Materials in the device could cause a systemic of local tissue reaction when the device comes in contact with the patient.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that scented deodorized menstrual pads be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safey and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 884 in Subpart F by adding new § 884.5425 as follows:

§ 884.5425 Scented deodorized menstrual pad.

(a) *Identification.* A scented deodorized menstrual pad is an absorbent cotton or synthetic material pad with fragrant chemicals added for the purpose of deordorizing. The device is used to absorb menstrual or other vaginal discharge. This generic type of device does not include devices with added drugs or antimicrobial agents.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 4, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 15, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[Docket No. 78N-1169]

[FR Doc. 79-9472 Filed 4-2-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 884]

Classification of Untreated Menstrual Pads

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying untreated menstrual pads into class I (general controls). The FDA is also publishing the recommendation of the Obstetrical and Gynecological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 4, 1979. The Commissioner of Food and Drugs

21 CFR Part 884

[Docket No. 78N-1168]

Obstetrical and Gynecological Devices; Classification of Menstrual Cups

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying menstrual cups into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: March 27, 1980.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION: FDA published in the Federal Register of April 3, 1979 (44 FR 19894), a proposed regulation explaining the development of the proposed regulations classifying obstetrical and gynecological devices, the medical device classification procedures, and the activities of the Obstetrical and Gynecological Device Classification Panel. FDA also published in that issue of the Federal Register (44 FR 19963) a proposed regulation to classify menstrual cups into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 884 in Subpart F by adding new § 884.5400, to read as follows:

§ 884.5400 Menstrual cup.

(a) *Identification.* A menstrual cup is a receptacle placed in the vagina to collect menstrual flow.

(b) *Classification.* Class II (performance standards).

Effective date: This regulation shall be effective March 27, 1980.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)))

Dated: January 23, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-5806 Filed 2-25-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 884

[Docket No. 78N-1169]

Obstetrical and Gynecological Devices; Classification of Scented Menstrual Pads

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying scented menstrual pads into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: March 27, 1980.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION: FDA published in the Federal Register of April 3, 1979 (44 FR 19894), a proposed regulation explaining the development of the proposed regulations classifying obstetrical and gynecological devices, the medical device classification procedures, and the activities of the Obstetrical and Gynecological Device Classification Panel. FDA also published in that issue of the Federal Register (44 FR 19964) a proposed regulation to classify scented or deodorized menstrual pads into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

1. One comment objected to classifying scented menstrual pads as devices on the grounds that these pads are not within the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)). The comment argued that there is no therapeutic intent or claim made for menstrual pads, that they are intended only to absorb menstrual flow, and that they are not intended to have any effect upon the structure or any function of the body. The comment conceded, however, that sterile menstrual pads sold to hospitals for use in medically indicated conditions are devices.

FDA disagrees with the comment's belief that scented menstrual pads are not devices. It is the agency's judgment that menstrual pads, by virtue of their intended purpose of collecting menstrual or other vaginal fluids, affect a function of the body, and therefore are within the act's definition of "device." This position is consistent with that taken by the agency in a letter dated February 11, 1977, from its Chief Counsel to a manufacturer of menstrual pads (Ref. 1).

2. A second comment argued that even if scented menstrual pads are devices, the long history of safe use of the pads justifies their exemption from the general controls applicable to devices. The comment specifically urged that manufacturers of these products be exempt from: (1) registration, listing, and premarket notification requirements, (2) recordkeeping and reporting requirements, and (3) good manufacturing practice requirements.

FDA disagrees with the comment. The agency believes that granting the exemptions suggested by the comment would not be in the public interest, that compliance with the requirements from which exemptions are suggested is necessary for protection of the public health, and that compliance is not unduly burdensome for manufacturers.

3. Another comment pointed out that the absorbent material most commonly used in scented deodorized menstrual pads is not cotton, but wood pulp. Therefore, the comment recommended that, in the identification, the word "cotton" be replaced by the word "cellulosic".

FDA agrees that the most commonly used material in scented menstrual pads is wood pulp. Both wood pulp and cotton are essentially cellulosic materials. To reflect accurately the materials used in these products, the agency is replacing the word "cotton" with the word "cellulosic" in the identification.

4. FDA has changed the name of the device to delete the word "deodorized," so that the device is now called the "scented menstrual pad." FDA has made this change and similar changes in the identification of the device because present commercial products actually are only scented, and are not deodorized. Menstrual pads treated with an antimicrobial agent or other drug would be regulated as drugs, not