fei PRODUCTS, LLC

2933 '03 JUN 12 A10:54

June 11, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Comments to Docket # 02N-0204
Bar Code Label for Human Drug Products and Blood; Proposed Rule
Federal Register Vol. 68, No. 50

Dear Sir or Madam:

Following a review of the United States Food and Drug Administration's (USFDA) proposed rule to require bar codes to be applied to all human drug prescription products, FEI Products, LLC (FEI) proposes that the human drug prescription product manufactured by FEI be exempt from this rule. FEI is the sole US manufacturer of the Copper T Model TCu 380A Intrauterine Copper Contraceptive (Copper T), which is made under specifications outlined in New Drug Application (NDA) 18-680. The Copper T is a plastic and copper type device regulated as a prescription drug. The Copper T is inserted, only by physicians in their practice setting, directly into the uterus with the aid of an insertion tube, solid rod (to hold the Copper T stationary), and a movable blue flange that is used to measure the depth of the uterus.

FEI believes that the administration of the Copper T for the purposes of this proposed rule is very similar to the position stated in the rule in regard to that of prescription drug samples. The Copper T is not sold in pharmacies, and can only be inserted by a physician or a trained clinician. As is stated in the proposed rule, the Agency does not believe that requiring the use of bar codes for a product that is utilized in a clinician's office and dispensed directly by a physician is necessary. For the reasons that drug samples are exempt from this proposed rule, FEI believes that the Copper T should be as well. FEI also believes that the Agency should explore a general exemption for products where the method of distribution requires insertion or otherwise physical intervention of the physician; for instance perhaps including products such as other IUD's or implantable devices or materials that are regulated as drugs by the Agency.

02N-0204 CS2

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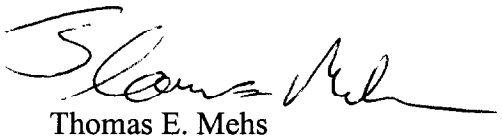
To further support this position, FEI also does not believe that applying a bar code to the Copper T Model TCU 380A furthers the Agency's stated aim of reducing medication errors for such products. The proposed rule outlines a number of reasons for possible medication errors. It is the belief of FEI that based on the method of administration of the Copper T (and potentially, the administration of other such products) errors either would not apply or would likely not be reduced by the application of a bar code. An explanation of why the error types identified in the rule would likely not apply to the Copper T is listed below.

1. "Administering the wrong doses" – The Copper T is a single use drug product, that is only manufactured in one dosage size.
2. "Administering a drug to a patient who is known to be allergic" – The labeling for the Copper T Model TCu 380A clearly indicates that copper allergy is a potential contraindication with the use of the Copper T. In addition, the presence of Copper on the drug is evident; FEI does not believe that a bar code would be beneficial in indicating to a doctor that there is copper present in the drug or that the patient has a copper allergy.
3. "Administering the wrong drug to a patient or administering a drug to the wrong patient" – The Copper T is inserted in a clinician's office and is generally inserted following an appointment. Due to the unique nature and design of the Copper T, it would be virtually impossible for a clinician to administer the wrong drug to a patient or to administer the drug to the wrong patient.
4. "Administering the drug incorrectly" – By nature of the Copper T, there is only one way to administer the drug. The method of application of the Copper T is more consistent with that of a medical device than with that of a drug.
5. "Administering the drug at the wrong time or missing doses" – The Copper T is not inserted in doses. There are no scheduled doses or multiple administrations of the drug. The time of administration is dependant upon a physician's evaluation of the patient (i.e. the patient is not pregnant).

For the reasons stated above, FEI respectfully requests that the Agency reconsider its position and establish a category of exemption for the Copper T and the relatively few other drug products that are either directly inserted or implanted into a patient by a physician in the doctors practice setting.

If you have any questions regarding this matter, please do not hesitate to contact me.

Sincerely,



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