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February 21, 2001

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BY HAND DELIVERY

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

Re: Medical Devices; Exemptions From Premarket Notification; Class II Devices. Pharmacy Compounding Systems [Docket No. 00P-1554]

Dear Sirs or Madams:

The undersigned provides these comments in opposition to the above referenced petition submitted to the Food and Drug Administration ("FDA") by Baxter Healthcare Corporation ("Baxter") and to request that the FDA deny this request to exempt these devices from the premarket notification requirement.

The justifications for this opposition to the petition and request for denial of the exemption are as follows:

1. Pharmacy Compounding Systems are used to mix multi-ingredient solutions used most commonly for Total Parenteral Nutrition, Caridoplegia Solutions, and Dialysis electrolyte replacement therapy. These large volume solutions are used to treat acutely and chronically ill patients. Numerous reports required by the Medical Device Reporting ("MDR") regulation have been filed historically due to adverse events associated with these treatments.

2. Exempting pharmacy compounding systems could lead to a host of new systems being introduced to the market. Firms that lack robust quality systems and design control practices without the benefit of

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premarket FDA oversight could potentially introduce these systems, leading to unintended patient harm or even death.

3. Manufacturers of these devices have received or are awaiting FDA clearance through the 510(k) premarket notification process. At least one such notification has over 500 pages of supporting documentation subject to review by the FDA. The petitioner, Baxter, has a large market share for pharmacy compounding systems and the nutritional solutions used by the systems. However, other potential manufacturers of these devices could be poorly prepared to market new and modified devices without the oversight provided by the 510(k) premarket notification review by the FDA. Moreover, the provisions of 21 C.F.R. Part 807, Subpart E, must remain in effect to assure that changes/modification to devices do not significantly affect safety or effectiveness. An exemption from 510(k) premarket notification would relieve manufacturers of the responsibility to comply with the current requirements of 21 C.F.R. Part 807, Subpart E, and deprive the public of the review by the FDA that it is entitled to expect.

4. The petitioner has not presented adequate support for its request. As a consequence of the Food and Drug Administration Modernization Act of 1997 ("1997 FDAMA"), the FDA review of premarket notifications appears to have become more efficient and decisions more timely. Because adverse events associated with use of these devices have been documented, premarket review by the FDA of new and/or modified devices by new and/or existing manufacturers provide a measure of public protection that is not burdensome.

In summary, the 510(k) premarket notification process provides the public with a method to assure the substantial equivalence of new and modified/changed devices. The devices for which the petitioner seeks an exemption perform a function for which compliance with the requirements of 21 C.F.R. Part 807, Subpart E, and issuance of an order by the FDA provide the public with reasonable assurance of device safety and effectiveness.

For these reasons, the undersigned respectfully requests that the FDA deny the petition and maintain the 510(k) premarket notification requirement for pharmacy compounding systems.

Cordially,

Larry R. Pilot

LRP/clb