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NORTH CAROLINA
BOARD OF PHARMACY



June 3, 1998

President
Jack G. Watts

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Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 123
Rockville, MD 20857

Re: Dockets Number 98N-0182
Bulk Drug Substances To Be Used in Pharmacy Compounding:
Request for Nominations

Dear Sir or Madame:

Pursuant to Section 127 of the Food and Drug Administration Modernization Act of 1997 the North Carolina Board of Pharmacy staff is nominating 24 bulk substances as candidates for the bulk drug list. These substances do not comply with the standards of an applicable USP or NF monograph nor are they components of drugs approved by the FDA, therefore supporting data is being provided to meet criteria set forth by FDA for inclusion on the list of bulk drug substances that may be used in compounding. Each nomination is contained in an individual folder which accompanies this letter including ingredient, chemical and common names. Chemical grade or description and information on how the ingredient is supplied is so annotated. Also, information about recognition in foreign pharmacopeias and bibliographies of available safety and efficacy data is included. Requirements such as information on dosage forms, strength and route of administration have been addressed along with stability data, any formulations or other miscellaneous information.

To support this data as requested by FDA, numerous documents and references have been included in each folder. For example, the melting point may be found on a quality control report or the description of a substance is contained on a certificate of analysis. Material Safety Data Sheets are included in every folder, which provide health hazard or toxicity data, reactivity data as well as handling precautions. Also included are monographs from *Martindale's Pharmacopeia* and *The Merck Index*. Where applicable each folder contains current abstracts and articles that further support doses, dosage forms, therapy guidelines and cross-over trials with results.

Very truly yours,

David R. Work
Executive Director

DRW/cl
Enclosures

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