FDA APPROVES BONE CEMENTS

The Food and Drug Administration announces approval of New Drug Applications for Methyl, Methacrylate* for cementing in place total hip replacement prostheses.

This approval makes available a significant new therapy for disabled patients. A significant number of such patients can now be at least partially rehabilitated through judicious use of this new material in orthopedic surgery.

The drug will be available for restricted use as specified in the package insert. (The manufacturer will mail each orthopedic surgeon a copy of this insert.)

The Food and Drug Administration wishes to express its appreciation to the American Academy of Orthopaedic Surgeons for help and cooperation during the approval process. Special appreciation also is due the orthopedic surgeons who served on the FDA's Ad Hoc Advisory Committee. Further, the FDA wishes to compliment the Academy on its current program to develop training courses in 23 centers to assist orthopedic surgeons in the proper use of this new drug.

*Surgical Simplex P Bone Cement and Surgical Simplex P Radiopaque Bone Cement, Howmedica

FAT LABELING

FDA is taking major initiatives to improve nutritional labeling of food products. Some of these efforts are of particular interest to physicians.

Of most interest, perhaps, are proposed changes in fat labeling. FDA has proposed regulations requiring product labels to give the name, source, and amount of fat content, and, on some foods, the amount and kind of fatty acids present. Under this proposal, such uninformative labeling as "shortening" or "vegetable oil" would be stopped.

FDA is proposing the fat labeling regulations to provide information to interested consumers and their physicians. The Agency is not recommending changes in dietary habits; neither is it taking sides in any medical discussion.

A related step by FDA is designed to make it possible for buyers to determine from the label the nutritional value of the food he is buying.

Several types of labels are being tested to measure effectiveness from the consumer's point-of-view. From these tests should come necessary information to evaluate consumer understanding, acceptance, and use of nutrient labeling.

ADVERSE DRUG REACTION REPORTING

The development and use of increasingly potent drugs has been accompanied by a significant incidence of adverse reactions. Recent reports indicate that as many as 5 percent of admissions to hospital medical services involve drug reactions and 15 percent of hospitalized patients suffer an adverse reaction during their stay.[1]

The Food and Drug Administration is taking steps to improve its adverse reaction surveillance and information programs. An initial move will be the appointment of an expert advisory committee to guide agency plans for improved methods of information gathering and dissemination to the medical profession.

The FDA also needs help from practicing physicians through voluntary reporting of adverse drug reactions. To aid participating physicians, a short reporting form has been prepared and pretested successfully at a number of major medical meetings, including a recent AMA meeting (Please see proposed form accompanying this Bulletin. When ready, a supply of forms will be mailed to practicing physicians.)

All physicians are urged to help; all physicians will share the results. But only insofar as the individual physician shows interest and participates will these results be meaningful. All information will be held in confidence. Later