

Over time, the plan is to complete the endowment and increase funding to support additional candidates and to offer support to candidates from other societies. The call for nominations for the 2020 meeting will be made in July of this year. The endowment fund remains open for both corporate and personal donations; for more information, visit www.mierf.org.

Those of us who have participated in the HCNMC over the years truly appreciate Dr. O'Brien's vision and

effort in creating a conference that brings together leaders from all branches of nuclear medicine and molecular imaging and continues to benefit all those who attend. For information about the conference, visit www.hcnmc.org.

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FDA Updates Bulk Drug Substances List

On March 1, the U.S. Food and Drug Administration (FDA) announced updates to the categories of bulk drug substances under its interim policy on compounding bulk drug substances under section 503B of the Federal Food, Drug, and Cosmetic Act. As previously reported in Newsline, SNMMI sent a petition to the FDA in 2018 requesting that arginine and lysine be added to the 503B bulks list or moved to the 503B Category 1 list.

SNMMI became aware of the issue through member feedback. In resulting recommendations to the FDA, SNMMI asked that the agency consider placing arginine and lysine on the 503B bulks list so that outsourcing facilities can use these 2 amino acids in compounding the amino acid solution for ¹⁷⁷Lu-DOTATATE (Lutathera; Advanced Accelerator Applications, Saint-Genis-Pouilly, France) treatment. According to the Lutathera package insert, an amino acid solution is to be administered to patients 30 minutes before and during administration of ¹⁷⁷Lu-DOTATATE. The amino acids arginine and lysine are recommended to minimize potential renal toxicity. A solution containing

only those amino acids is not commercially available. They are offered only in combination with other amino acids and substances that may cause patients significant discomfort, including nausea and vomiting. To remedy this, additions to the 503B Bulk Drugs Category 1 list now include: arginine hydrochloride, L-arginine hydrochloride, L-lysine hydrochloride, and lysine hydrochloride.

SNMMI commended the FDA on March 4 for the agency's swift action to update the 503B Bulk Drugs list, a move that will ultimately make it easier for manufacturers to compound and make available an arginine/lysine-only solution. This will help patients with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors to better tolerate and thereby benefit from ¹⁷⁷Lu-DOTATATE therapy. For more information see <https://www.federalregister.gov/documents/2019/03/04/2019-03810/list-of-bulk-drug-substances-for-which-there-is-a-clinical-need-under-section-503b-of-the-federal>.

*SNMMI
U.S. Food and Drug Administration*