Endo Ventures Limited
Minerva House,
Simmonscourt Road,
RDS,
Ballsbridge, Dublin 4,
D04 H9P8
Ireland

August 26, 2022

To: Whom it may concern

Re: ***SDS request for Alvimopan Capsules,***
Endo / Par Actions in Response to USP 800 and SDS Requests

Dear Sir / Madam:

USP 800 applies only to the use of certain hazardous pharmaceutical products in the healthcare setting and is not applicable to pharmaceutical manufacturers such as Endo/Par. Further, OSHA regulations provide that solid dosage form drugs (such as tablets and capsules) for direct administration to a patient and drugs packaged for sale to consumers in a retail establishment do not require Safety Data Sheets.[1] The product referenced in your inquiry is packaged for sale directly to a consumer and therefore is exempt from the Safety Data Sheet requirement.

Although no Safety Data Sheets are required for finished Pharmaceutical Products meeting the above referenced criteria, the prescribing information for Endo / Par products may provide Safe Handling, Warnings, or Precautions to be taken when handling or taking the product.

In addition, the requested product is not regulated as hazardous material for shipping in accordance with the U.S. Department of Transportation, and has no hazardous storage limitations as defined by the National Fire Protection Association.

We hope that the information above satisfactorily addresses your questions.

Sincerely,

Mr. Mick McGuinness
Senior Vice President
Global Quality & Compliance

[1] Safety data sheets are not required for "[a]ny drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies)" 29 C.F.R. § 1910.1200(b)(6)(vii).