# 6. NOVEL EXCIPIENTS [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

For excipients used for the first time in a drug product or by a new route of administration, full details of manufacture, characterization, and controls, with cross-references to supporting safety data (nonclinical and/or clinical), should be provided according to the drug substance format. Requirements for the excipient should be discussed with the FDA prior to application.