

Notice of Intent: Reporting Requirements

For proposed proprietary names that are being submitted as part of an IND, NDA, BLA, ANDA, or supplement reviewed by CDER, contact Carol Holquist by e-mail at proprietarynamereview@fda.hhs.gov. Applicants should provide the following information in the e-mail for registration:

- o E-mail subject heading: “PNR Pilot Program for CDER/DMEPA”
- o First sentence in e-mail should indicate: “Request for Registration in PNR Pilot Program”
- o Company name
- o Name of U.S. regulatory contact (include telephone number and e-mail address)
- o Name of entity conducting proprietary name analysis (applicant company or third-party vendor)
- o Application type (IND, NDA, BLA, ANDA, or supplement) and application number
- o Proposed proprietary name (identify primary and alternate proprietary name, if any)
- o Approximate (requested) month for intended submission