Naloxone for Outpatient Use: Data Required to Support an NDA

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Regulatory Approach

Two regulatory pathways: 505(b)(1) or 505(b)(2)

- 505(b)(2)
  - An application submitted …for a drug for which the investigations … relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted

Regulatory Approach

Two regulatory pathways: 505(b)(1) or 505(b)(2)

- A 505(b)(2) application may rely upon the Agency's previous finding of safety and effectiveness of a drug product approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act (i.e., NDAs).
- To rely on the Agency's previous findings, must establish a "bridge" (e.g., via comparative bioavailability, or relative BA data) between proposed product and each reference drug to demonstrate that such reliance is scientifically justified.

Naloxone Hydrochloride

- Indicated for the complete or partial reversal of narcotic depression, including respiratory depression, induced by opioids

- Also indicated for the diagnosis of suspected acute opioid overdosage.

Naloxone Hydrochloride

- After a satisfactory response, patient should be kept under continued surveillance and repeated doses of naloxone should be administered, as necessary, since the duration of action of some narcotics may exceed that of naloxone.
- Naloxone is not effective against respiratory depression due to non-opioid drugs. Reversal of buprenorphine-induced respiratory depression may be incomplete.

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