

INSTRUCTIONS FOR COMPLETION OF FORM FDA 2301

Copies of this form may be obtained by writing to:

Department of Health and Human Services
Public Health Service
Food and Drug Administration (HFV-12)
7519 Standish Place, Room 3508
Rockville, MD 20855

1. Enter the NADA number assigned to the drug. If fewer than six digits, add leading zeros.
7. A combined report may be submitted for NADAs or ANADAs that provide for preparations containing the same new animal drug ingredient(s). A separate Form FDA-2301 should be completed for each NADA included in the combined report; the primary NADA should also be identified on each such separate Form FDA-2301. Reports for all NADAs involved should be submitted on the anniversary date of the earliest approved NADA involved (primary NADA). All information common to each such periodic report may be submitted under the primary NADA number (combined report) and referenced in the individual reports for other NADAs involved. All other information specific to a particular NADA must be submitted in a separate report under that NADA.

The report for the primary NADA should reference all other involved NADA numbers under item 7. The report for each other NADA should reference the primary NADA number under item 7. (See 510.300(b)(4)(ii).)
9. Check this box if report is a follow-up to one previously submitted or is a response to an FDA request.
- 10(a). An adverse experience to an animal drug is defined as "an unexpected side effect or unintended change in the structure, function or chemistry of the body, including injury, toxicity, sensitivity reaction, or any unexpected increase in incidence or severity thereof, or lack of effectiveness associated with clinical use of the drug" and should be reported whether or not determined to be attributable to the drug.
- 10(a)(1). Enter total number of complaints being reported. Each complaint may involve one or more adverse drug reactions. A complaint is defined as a report involving one situation or incident and may involve one or more animals.
- 10(a)(4). Enter total number of animals experiencing reactions involved in item 10(a)(3).
- 10(g). Report the quantity marketed in units of highest concentration and the largest marketing package size. In the case of a dosage form product, e.g., tablets which are formulated on body weight range basis, give the quantity marketed of specific strength and package size separately without converting into highest concentration and the largest marketing package size unit.

Submit two copies of the report to:

Department of Health and Human Services
Public Health Service
Food and Drug Administration (HFV-199)
7500 Standish Place, Room N403
Rockville, MD 20855

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

**Department of Health and Human Services
Public Health Service
Food and Drug Administration (HFV-199)
7519 Standish Place, Room 3508
Rockville, MD 20855**

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.