

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The OMB control number for this information collection is 0579-0327. The time required to complete this information collection is estimated to average 15 hours 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.

**OMB
Approved**
0579-0327
EXP.:
XX/XX/XXXX

UNITED STATES DEPARTMENT OF
AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION
SERVICE
VETERINARY SERVICES

**MANUFACTURER APPLICATION
FOR APPROVAL OF OFFICIAL
ANIMAL IDENTIFICATION
DEVICES**

Submission of this form by a device manufacturer indicates that they agree to follow the procedures for approval of official animal identification methods and devices contained in the Animal Disease Traceability (ADT) General Standards document and submit all required supporting documentation (see ADT General Standards Part C. Approval of Official Identification Methods and Devices for Animals and the associated appendices, and 9 CFR 79.3(k) for sheep and goats). For more information on ADT and official identification devices visit the ADT Website at <http://www.aphis.usda.gov/traceability/>.

Purpose of Application

| | | |
|---|---|---|
| <input type="checkbox"/> Initial (Proposed field trial protocol attached) | <input type="checkbox"/> Final (Device approval and sales data from other countries OR field trial summary report attached) | <input type="checkbox"/> Modification of an approved device (Original and proposed specifications, field trial data and/or approval and sales data from other countries (as applicable) attached) |
|---|---|---|

Device Applicant Information

| | | | |
|---|----------|---------------------------------------|--------------|
| Name: | | Nonproducer Participant Number (NPN): | |
| Street Address : | | | |
| Street Address 2: | | | |
| City: | | State: | Postal Code: |
| Phone: | Email: | | |
| Primary Contact First Name: | | Last Name: | |
| Phone: | Phone 2: | Email: | |
| Do you plan to be a device/tag manager? (Distribute the approved device) <input type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| What is the company's role regarding this device? <input type="checkbox"/> Complete manufacturing, imprinting, and encoding (Radio Frequency Identification (RFID only)) <input type="checkbox"/> Encoding and/or Imprinting only <input type="checkbox"/> US Device Manager only (foreign manufacturer) | | | |
| What is the bi-weekly production capacity for this device? | | | |
| What is the anticipated inventory for this device? | | | |

Manufacturing Plant Information (if different than above)

NOTE: If more than one manufacturer provide additional contact information and locations on a separate sheet

| | | | |
|-----------------------------|----------|------------|--------------|
| Business Name: | | NPN: | |
| Street Address: | | | |
| Street Address 2: | | | |
| City: | | State: | Postal Code: |
| Country: | Phone: | Email: | |
| Primary Contact First Name: | | Last Name: | |
| Phone: | Phone 2: | Email: | |

| |
|--|
| What is the bi-weekly production capacity for this device? |
| What is the anticipated inventory for this device? |

| Device Information | |
|---|----------------------------|
| NOTE: If requesting a modification to an existing approved identification device complete the information below with the new device specifications. | |
| Device Name: | Manufacturer Product Code: |
| Required International Committee for Animal Recording (ICAR) Conformance and Performance certifications attached: <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| ICAR Product code: | ICAR Approval date: |
| Device Format: <input type="checkbox"/> Eartag <input type="checkbox"/> Injectable transponder <input type="checkbox"/> Other (describe): | |
| Physical Characteristics: <input type="checkbox"/> One Piece <input type="checkbox"/> Two Piece | |
| Shape: <input type="checkbox"/> Round <input type="checkbox"/> Rectangle <input type="checkbox"/> Strip <input type="checkbox"/> Other (describe): | |
| Primary Material: | |
| High resolution pictures and diagrams showing all aspects of the device including materials used in each component and measurements (including pictures of all print formats and colors for which approval is requested for sheep and goats tags) emailed to traceability@usda.gov . <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |

| Species | |
|---|--|
| NOTE: USDA reserves the right to approve methods of identification specific to each species. Additionally, the use of injectable transponders in food animals is subject to FDA and FSIS regulations. Injectable transponders are not an approved official identification method for bison and cattle. | |
| <input type="checkbox"/> Alpaca/Llama <input type="checkbox"/> Cattle/Bison <input type="checkbox"/> Deer/Elk <input type="checkbox"/> Horses <input type="checkbox"/> Sheep/Goats <input type="checkbox"/> Swine | |

| Device Details | |
|--|--|
| <input type="checkbox"/> Low Frequency (LF) 134.2 kHz (must conform to ISO 11784 and 11785) Technology type: <input type="checkbox"/> HDX <input type="checkbox"/> FDX | |
| <input type="checkbox"/> UHF Numbering Format: <input type="checkbox"/> Animal Identification Number (AIN) <input type="checkbox"/> National Uniform Eartagging System (NUES) | |
| <input type="checkbox"/> Dual (combined low and ultra-high) Frequency Eartag (AIN Numbering format only) | |
| <input type="checkbox"/> Visual Only | |
| For technologies other than RFID: Please contact ADT Program Staff at traceability@usda.gov | |

| Performance and Quality Controls | |
|---|--|
| I certify that the identification device submitted for approval meets all performance and conformance requirements as defined in the ADT General Standards | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Description of the quality control measures detailing the ability to produce and distribute the device consistently and according to the specifications contained in the ADT General Standards including, the full quality control plan and flow diagram for this identification device from manufacturing of all components, encoding and/or imprinting, shipment and addressing consumer complaints attached. If more than one company is involved with the manufacturing of the device components a full quality control plan is attached for the entity that performs each step and their location. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If requesting approval for a sheep and goat identification device, a signed Company Agreement for Approval to Produce Official Eartags for Sheep and Goats is attached | <input type="checkbox"/> Yes <input type="checkbox"/> No |