Standard License Restrictions

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Source Document: CVB Quality Manual (current version) Chap 7

Product licenses may be issued with one or more restrictions. Some types of licenses always require restrictions. Restrictions may be considered on a case-by-case basis for others. Table 1 includes a list of such products. Review this list when licensing new products OR reissuing existing licenses, as the need for certain restrictions may change over time. Table 2 provides the text that corresponds to a particular restriction number.

Table 1.

Product/Fraction	**Required Restrictions (by LSRTIS Number)**	**Additional Restrictions to Consider (by LSRTIS Number)**
Anaplasma Marginale Vaccine	42	
Allergenic Extract	42	
Antivenom	42	
Autogenous	55	
Avian Pneumovirus, live/modified live	42, 43, 44	
Avian Reovirus Vaccine, Killed	43	
Avian Influenza Vaccine (turkeys, non-H5, non-H7	43, 46	60
Avian Influenza vaccine (turkey H5, turkey H7, all chicken	43, 46, 58	60
Babesia caballi	45	
Babesia equi	45	
Bovine spongiform encephalopathy diagnostics	45, 62, 343	46
Bronchitis Vaccine, Live Virus (except Mass & Conn)	43	
Brucella abortus (vaccines & kits)	42, 43	
Bursal Disease Vaccine, Live Virus	43, 47	
Bursal Disease Vaccine, Killed	43	
Cancer products	42	
Conditional licenses (“regular”)	43, 46, 48, 49, 50, 56, 480	42, 54, 57
Chronic wasting disease diagnostics	45, 62	
Duck enteritis virus	43	
Ehrlichia risticii	43	
Equine arteritis virus, live	43	
Equine infectious anemia diagnostics	45	
Feline immunodeficiency virus (vaccine)	42	54
Mycobacterium bovis diagnostics	42, 43	
Mycobacterium paratuberculosis (vaccines and kits)	43	

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Product/Fraction	Required Restrictions (by LSRTIS Number)	Additional Restrictions to Consider (by LSRTIS Number)
Mycobacterium tuberculosis diagnostics	42, 43	
Mycoplasma gallisepticum (vaccine & kits)	43	
Mycoplasma synoviae (vaccines & kits)	43	
Permitted products	64, 186	186 may be exempted from products for USDA emergency use if the Outline of Production has adequate assurances regarding Ingredients of Animal Origin (IAO) source/testing and a statement that IAO sources/testing will not change without approval of CVB
Pigeon Pox Vaccine, live	60	
Platform Products (conditional)	43, 46, 48, 50, 56, 71	Contact PEL Director before licensing a platform product, as some restrictions are still being discussed.
Prescription Products	42, 43, 46, 48, 50, 54, 55, 56, 57, 132, 200, 540	
PRRS virus, live and modified live	47	
Pseudorabies virus (vaccine & kits)	43, 45	
Rabies virus	43	
Scrapie diagnostics	45, 46, 62	
Streptococcus equi (whole cell bacterin)	42	
Tenosynovitis virus, live and modified live	43	
Tuberculin	42, 43	
Vibrio salmonicida	43	
Products for disease exotic to U.S.	52	46
Products with wildlife claims		46, 58, 61, 62
Components of combination packages in which firm with comb.pkg license does not have a significant step in production of the component	53	
For further manufacture products	51	

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Product/Fraction	Required Restrictions (by LSRTIS Number)	Additional Restrictions to Consider (by LSRTIS Number)
Products for diseases appearing on OIE list		45, 46
Biotechnology-derived products containing live vectors that can replicate in the vaccinated animal		46
Products with Additional Reporting Requirement		57
Products that are tested at a contract facility for any Section V test	70	
Products with target animal safety testing exemption	57 (yearly)	
Diagnostic products that indicate use for revaccination recommendations	72	
Diagnostic products that allow use of IAOs from countries of concern	73	

Table 2.

LSRTIS License Restriction Number	Restriction
42	For use by, or under the supervision of, a veterinarian.
43	Distribution in each State shall be limited to authorized recipients designated by proper State officials--under such additional conditions as these authorities may require.
44	The distribution and use of this vaccine shall be limited to <specify state(s) and/or foreign countries>.
45	Sale and use in the United States restricted to laboratories approved by State and Federal (USDA) animal health officials.
46	Export distribution shall be limited to authorized recipients designated by proper animal health regulatory officials--under such additional conditions as these authorities may require.
47	Recommended use shall be restricted to premises having a history of the disease.
48	Reissuance of this license shall be considered in accordance with 9 CFR Part 102.6.
49	The following statement shall appear on all labels: This product license is conditional. Efficacy and potency test studies in progress.
50	Trade Names shall not be used with this product.
51	For further manufacture.
52	For Export Only.
53	This product may only be marketed as a component of <other Product Codes>.
54	Marketing and promotional materials must be reviewed by the CVB prior to publication or distribution.
55	This license does not authorize production, distribution, or shipment of a vaccine/bacterin for foot-and-mouth disease, rinderpest, any H5 or H7 subtype of avian influenza, any subtype of avian influenza in chickens, swine vesicular disease, Newcastle disease, African swine fever, classical swine fever, Brucella abortus, vesicular stomatitis, and rabbit hemorrhagic disease or any other disease the Administrator determines may pose a risk to animal or public health.
56	This license will terminate on <specify date or length of time>.
57	Unusual conditions or adverse events linked to vaccinated animals are to be reported to the CVB <specify reporting interval>.
58	Domestic distribution and use shall be under the supervision or control of USDA, APHIS, Veterinary Services, as part of an official USDA animal disease control program.
59	Recommended use shall be restricted to healthy 10- to 17-week-old broiler breeder replacement chickens and to premises where no other susceptible chickens are maintained.

60	For use in <specified species> only.
61	Restricted to use in State or Federal Rabies Control Programs.
62	Potency testing and distribution and use shall be under the supervision or control of USDA, APHIS, Veterinary Services--under such additional conditions as these authorities may require.
63	Serials may be released, subject to immediate recall, should the Master Seed/Cell Stocks, now under test by APHIS, be found unsatisfactory.
64	The producer/permittee agrees to submit to periodic reinspections of the production facility under terms to be specified in a Cooperative Agreement between the parties. The permittee agrees to be responsible for all costs associated with these inspections.
70	The CVB has the authority to inspect TGA Sciences, Inc., No. T100, that performs the Serology, Clostridium botulinum Type B potency test contracted by the Licensee.
71	The license may be renewed upon request by the firm and at the discretion of APHIS based on product performance, safety profile, manufacturing consistency, and inspections by the CVB.
72	Recommendations for use of this diagnostic product may not imply that the test results are approved for making recommendations regarding revaccination.
73	Use of this diagnostic product is restricted. Labeling must bear the following statements: “Do not use in the direct presence of animals. This product contains ingredients that may be contaminated with foreign animal diseases of concern. Inactivate all unused contents before disposal.”
132	Disposition records, maintained according to 9 CFR 116.2, shall be prepared in a format acceptable to APHIS and submitted to CVB at intervals determined by APHIS.
186	Each shipment of biological product distributed and sold under this permit must be accompanied by an original certificate endorsed by a full-time, salaried veterinarian of the agency responsible for animal health of the Government of <specify country>, or other assurances acceptable to APHIS, certifying that: 1.) Ingredients of animal origin are sourced from the United States or countries considered free, low risk, or not affected with foreign animal diseases of concern and with negligible or controlled risk of Bovine Spongiform Encephalopathy [BSE], according to APHIS' Animal Disease Status designations as defined in Veterinary Services Memorandum 800.51. 2.) During the manufacturing process, the manufacturing facility does not receive, store, or process any ingredients of ruminant origin from countries with BSE. 3.) The product complies with all other provisions of 9 CFR 113.53.
200	The license may be renewed upon request by the firm and at the discretion of APHIS based on manufacturing consistency and

	inspections by the CVB. For use as a veterinary prescription. Efficacy and potency have not been demonstrated.
343	Use of this kit is restricted to testing conducted as part of the official USDA BSE surveillance program.
344	Product imported under this permit may only be received by USDA personnel or persons designated by the USDA, as part of an official USDA animal disease control program.
480	The licensee shall demonstrate acceptable progress toward completion of host animal efficacy and potency test studies in accordance with acceptable protocols filed with the CVB prior to reissuance.
540	Marketing and promotional materials are restricted to licensed veterinarians.
551	This license restricted to antigens from the VP7 gene from an individual Rotavirus Strain C isolate.