Justification for Change

Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73)

(OMB Control No. 0920-0576) Expiration 10/31/2020

Non-Substantive Change Request

Centers for Disease Control and Prevention

Office of Public Health Preparedness and Response

Division of Select Agents and Toxins

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Nonmaterial/non-substantive change to an OMB approved information collection for Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73) (OMB Control No. 0920-0576) Expiration 10/31/2020

Justification for the Change - A nonmaterial/non-substantive can be explained in table format as shown below:

Form	Current Item	Requested Change	Justification
APHIS/CDC Form 4, Section B, Block 1	"1. Select Agent or Toxin Identified:"	If "Botulinum neurotoxins" is selected from drop down box. Question is added "If Botulinum neurotoxins identified in Block #1, will you attempt to isolate Botulinum neurotoxin producing species of Clostridium? Yes (if yes, an update answering questions 1b and 1c is required within 7 days of identification) No" If yes, then, questions 2 & 8 of current form are asked.	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 4 Guidance, Page 6	Block B1 – Select Agent or Toxin Identified:	Add to Block B1, a bullet that states "If Botulinum neurotoxins identified in Block #1, complete block 1a. If yes is selected for block 1a, complete blocks 1b and 1c by using instructions provided below for "Block B2 – Date Identified:" and "Block B8 – Disposition of Select Agent or Toxins."	

Mini Supporting Statement

Justification for Change

This is a request for nonmaterial/non-substantive change clarifies the meaning/intent of the question for the select agent or toxin identified. In the list of select agents and toxins, there is a toxin Botulinum neurotoxins that is produced by the select agent, Botulinum neurotoxin producing species of *Clostridium*. The APHIS/CDC Form 4, Report of the Identification of a Select Agent or Toxin, is used by clinical or diagnostic laboratories and other entities to notify the Federal Select Agent Program of the identification of a select agent or toxin as the result of diagnosis, verification, or proficiency testing and of the final disposition of that identified agent or toxin. In the case of Botulinum neurotoxins, the entity also reports Botulinum neurotoxin producing species of *Clostridium* for the same specimen. To reduce the burden of having an entity report by submitting two APHIS/CDC Form 4 for the same specimen. The nonmaterial/non-substantive change is to clarify Section B, Block 1 if "Botulinum neurotoxins" is selected from drop down box, then the question is to clarify if the agent will then be reported. It will also collect the identification date of the agent and disposition of specimen. Currently, there are approximately 8 entities that report about 120 additional forms annually both the agent and the toxin.

Using the data obtained from the 2016 Annual Report of the Federal Select Agent Program (https://www.selectagents.gov/resources/FSAP_Annual_Report_2016.pdf) the Division of Select Agents and Toxins received 1,030 reports in 2016. The public reporting burden of providing this information is estimated to average 30 minutes per response. We would be reducing 120 forms for these approximate 8 entities by implementing this nonmaterial/non-substantive change. Therefore, reducing the public burden by 60 hours from the approved 515 hours to 455 hours. The nonmaterial/non-substantive change will not affect the burden for the other select agents and toxins reported by using the APHIS/CDC Form 4.