SB0083S01 compared with SB0083

~~{deleted text}~~ shows text that was in SB0083 but was deleted in SB0083S01.

inserted text shows text that was not in SB0083 but was inserted into SB0083S01.

DISCLAIMER: This document is provided to assist you in your comparison of the two bills. Sometimes this automated comparison will NOT be completely accurate. Therefore, you need to read the actual bills. This automatically generated document could contain inaccuracies caused by: limitations of the compare program; bad input data; or other causes.

Senator Curtis S. Bramble proposes the following substitute bill:

COSMETIC MANUFACTURING CERTIFICATE PROGRAM

2022 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Curtis S. Bramble

House Sponsor: _____

LONG TITLE

General Description:

This bill authorizes the Department of Agriculture and Food to ~~{regulate cosmetics, including by issuing certificates for}~~issue good manufacturing practices certificates to cosmetic manufacturers.

Highlighted Provisions:

This bill:

- defines terms;
- ~~{ transfers the authority to regulate cosmetics from the Department of Health to the Department of Agriculture and Food;~~
- ~~}~~ requires the Department of Agriculture and Food to create a process for issuing good manufacturing practices certificates to cosmetics manufacturers; and
- makes technical and conforming changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

~~{AMENDS:~~

~~**26-1-23.5**, as renumbered and amended by Laws of Utah 1991, Chapter 112~~

~~}~~ENACTS:

4-2-801, Utah Code Annotated 1953

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **4-2-801** is enacted to read:

Part 8. Cosmetics

4-2-801.~~{ Regulation of cosmetics -- Good}~~ Good manufacturing practices for cosmetics.

(1) As used in this section:

(a) "Cosmetic" means the same as that term is defined in 21 U.S.C. Sec. 321.

(b) "Good manufacturing practices" means the current good manufacturing practices described in the United States Food and Drug Administration's Guidance for Industry: Cosmetic Good Manufacturing Practices.

~~{~~ ~~(c) "ISO 22716 certificate" means a certificate from an external certification body that certifies that the certificate holder is in compliance with the guidelines for cosmetics described in the current version of the International Organization for Standardization's ISO 22716:2007.~~

~~(d) "Manufacture" means to make, for sale, a cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the cosmetic product.~~

~~}~~ (2) (a) In accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, and consistent with this section, the department shall make and enforce rules establishing a voluntary certification program for ~~{the manufacture, sale, and distribution of}~~good manufacturing practices for cosmetics, including~~{ rules establishing}~~:

(i) the criteria for receiving a good manufacturing practices certificate, ~~{in accordance~~

~~with Subsection (4); and}~~including the qualifications for registering with the department as required by Subsection (3)(a);

(ii) the process to apply for and receive a good manufacturing practices certificate under this section~~{.~~

~~(}~~; and

(iii) criteria by which the department will determine the term of a good manufacturing practices certificate in accordance with Subsection (5).

(b) Rules made pursuant to this section may not be more stringent than~~{ those}~~:

(i) rules established by federal law~~{.}~~; or

(~~{(3) The department shall establish and operate a program for issuing good manufacturing practices certificates for cosmetics.~~

~~(4) The}~~ii) guidance published by the United States Food and Drug Administration.

(3) The department's good manufacturing practices certification program shall provide for the issuance of a certificate to an applicant if:

(a) the applicant is registered with the department pursuant to registration requirements established by the department under Subsection (~~{i}~~2)(a);

(b) the applicant submits an application to the department ~~{that requests an inspection of}~~requesting a certificate for the applicant's manufacturing facility; and

(~~{ii}~~c) the department inspects the applicant's manufacturing facility and determines that the applicant is in compliance with good manufacturing practices~~{; or~~

~~(b) the applicant submits an application to the department and provides the department with an acceptable ISO 22716 certificate.~~

~~(5) (a) The department may not conduct an inspection under Subsection (4)(a) except at the request of an applicant.~~

~~(b) The department shall complete an inspection under Subsection (4)(a) within 28 days after the day on which an applicant requests the inspection in connection with a completed application for a good manufacturing practices certificate.~~

~~(6)}~~.

(4) (a) In accordance with Section 63J-1-504, the department shall adopt a schedule of registration and certificate fees to cover the department's costs of ~~{conducting inspections under Subsection (4)(a)}~~administering the certification program described in this section.

(b) Notwithstanding Section 63J-1-504, the department shall retain the fees as dedicated credits~~{ and may only use the fees to conduct inspections under Subsection (4)(a)}~~.

(~~{7}~~5) A good manufacturing practices certificate issued under this section shall:

(a) specify the certificate issuance date and expiration date~~{~~.

~~Section 2. Section **26-1-23.5** is amended to read:~~

~~**26-1-23.5. Rules for sale of drugs and medical devices.**~~

~~The department shall establish and enforce rules for the sale or distribution of human drugs[, cosmetics,] and medical devices. The rules adopted under this section shall be no more stringent than those established by federal law.~~

~~}~~; and

(b) be valid for a term of one to three years as determined by the department pursuant to criteria established under Subsection (2)(a).