

PURE BIOSCIENCE, INC.
Form 8-K
November 10, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 10, 2014

PURE BIOSCIENCE, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

001-14468
(Commission

File Number)

33-0530289
(IRS Employer

Identification No.)

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1725 Gillespie Way

El Cajon, California

92020

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: (619) 596-8600

Not applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- .. Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- .. Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- .. Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- .. Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Items.

On November 10, 2014, PURE Bioscience, Inc (the Company) announced that it has withdrawn the Food Contact Notification (FCN) it submitted to the U.S. Food and Drug Administration (FDA) in July 2014 for the use of SDC in raw poultry processing. The Company decided to withdraw its FCN, without prejudice, following its receipt of a Deficiency Letter from the FDA stating that the agency has developed new data that calls into question the long established safety levels of the cumulative dietary intake of silver in the US resulting from the food contact uses the agency had previously approved. As a result, the FDA indicated that it would not approve the Company s FCN absent new data or additional information that adequately addresses its new toxicity concerns.

The Company also announced that it would likely receive a similar Deficiency Letter from the FDA for the FCN it submitted in October 2014 for the use of SDC to reduce Salmonella, E. coli and Listeria in the processing of produce. If it does receive such a Deficiency Letter, the Company announced that it intends to similarly withdraw that FCN until it can provide the FDA with the additional data and information necessary to address the FDA s concerns.

A copy of the Company s press release is filed herewith as Exhibit 99.1, and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release, dated November 10, 2014.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PURE BIOSCIENCE, INC.

Dated: November 10, 2014

By: /s/ Henry R. Lambert
Henry R. Lambert
Chief Executive Officer

EXHIBIT INDEX

<i>Exhibit Number</i>	<i>Description</i>
99.1	Press Release, dated November 10, 2014.