DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/6/2026-4/15/2026* FEI NUMBER 2022039

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David V. Butler , President

FIRM NAME	STREET ADDRESS
Scientific Pharmaceuticals, Inc.	3221 Producer Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pomona, CA 91768-3916	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

A design and development file was not maintained for each medical device type or medical device family.

Specifically,

Your firm failed to establish and maintain a Design and Development File containing design and development plan, design inputs, design outputs, design validation/design verification, design review and design transfer for the Class II Medical Device, CuRay Match Flowable Composite Restorative. This device has been sold and distributed since 1979 and received FDA 510k Clearance in 1983.

OBSERVATION 2

Processes for production and service provision where the resulting output cannot be, or is not, verified by subsequent monitoring or measurement were not validated.

Specifically,

Your firm's retrospective process validation, Evaluation Report: Validation of the (b) (4)

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/6/2026-4/15/2026* FEI NUMBER 2022039

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
David V. Butler , President	
FIRM NAME Scientific Pharmaceuticals, Inc.	STREET ADDRESS 3221 Producer Way
CITY, STATE, ZIP CODE, COUNTRY Pomona, CA 91768-3916	TYPE ESTABLISHMENT INSPECTED Manufacturer

(b) (4) Document # (b) (4) Dated 01/07/2020 does not demonstrate that the mixing process consistently produces product meeting predetermined requirements for the Class II Medical Device, CuRay-Match Visible Light-Cured Flowable Composite Restorative and Veneer Cement, Resin-Based Restorative Material.

a.) Your firm's Quality Manager stated that the validation of CuRay-Fil Composite Restorative (b) (4) (b) (4) is similar of CurRay-Match Visible Light-Cured Flowable Composite Restorative and Veneer Cement, Resin-Based Restorative Material (b) (4) However, this validation report does not provide a documented justification demonstrating product equivalency, formulation similarity, or equivalent critical quality attributes.

b.) The report does not define process parameters of mixing time, mixing speed, temperature and batch size. In reference to Section (b) (4) of the validation report (b) (4)

(b) (4)

(b) (4) The validation does not reference or establish documented mixing procedures specifying critical process parameters. Section (b) (4) describes only general operation instructions without defining validated parameters for time, speed, temperature or batch size ranges.

c.) The validation report (b) (4) utilizes past routine production data without evaluation of worst-case conditions including minimum and maximum batch sizes, mixing times, temperature, speeds, or bowl fill levels. Additionally, the validation presents only (b) (4) quality control test results (b) (4) without process parameter data such as (b) (4) mixing times, temperature, speeds, or in-process monitoring data. Historical data is limited to pass/fail results and does not demonstrate process control during manufacturing.

d.) The validation has referenced specification changes for consistency/viscosity using the (b) (4) from (b) (4) documented on Page (b) (4) and Page (b) (4) of the validation report (b) (4) following equipment replacement in late 2017. The new equipment resulted in a new acceptability range (b) (4) due to new and completely different methodology, but no validation was performed.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/6/2026-4/15/2026*
	FEI NUMBER 2022039

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
David V. Butler , President	
FIRM NAME Scientific Pharmaceuticals, Inc.	STREET ADDRESS 3221 Producer Way
CITY, STATE, ZIP CODE, COUNTRY Pomona, CA 91768-3916	TYPE ESTABLISHMENT INSPECTED Manufacturer

OBSERVATION 3

Processes needed for product realization were not adequately planned and developed.

Specifically,

Your firm failed to establish, document, and maintain adequate processes for risk management throughout the product lifecycle for CuRay Match Flowable Composite Restorative products.

a.) In review of General Product Report, (b) (4) for CuRay Match Flowable Composite Restorative. Your firm has not established documented processes that integrate risk management throughout the stages of design and development and has failed to document risk estimation for CuRay Match Flowable Composite Restorative prior to implementation of risk control measures. Table (b) (4) shows "Initial Risk Index" values ranging from (b) (4) (b) (4) for (b) (4) identified failure modes, but no documented evidence was available showing how these initial risk values were estimated for CuRay Match specifically for the following:

- The probability of occurrence of harm for each hazardous situation
- The severity of harm for each hazardous situation
- The basis for the initial risk index values assigned
- The information or data used to estimate risk for CuRay Match's specific design, materials, manufacturing processes, and use conditions.

b.) Your firm failed to define and implement an adequate method for evaluating the combined effect of all residual risks. Per your Risk Management Procedure OP-21-01, Section 8.1.5.6, states the methodology to evaluate overall residual risk is *done through a* (b) (4) (b) (4) but does not describe the method for evaluating the cumulative effects of all residual risks taken together. No documentation was available for gathering and reviewing data on similar

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Marlo-Ian M Alintanahin, Investigator X Marlo-Ian M Alintanahin Investigator Signed By: Marlo Ian M. Alintanahin -S Date Signed: 04-15-2026 13:34:18	4/15/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/6/2026-4/15/2026*
	FEI NUMBER 2022039

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
David V. Butler , President	
FIRM NAME Scientific Pharmaceuticals, Inc.	STREET ADDRESS 3221 Producer Way
CITY, STATE, ZIP CODE, COUNTRY Pomona, CA 91768-3916	TYPE ESTABLISHMENT INSPECTED Manufacturer

devices, published literature, or expert judgment to evaluate whether the overall residual risk posed by the device as a whole is acceptable. Section (b) (4) of the General Product Report (b) (4) (b) (4) states, (b) (4)

(b) (4)

c.) Your firm failed to document implementation and verification of risk control measures, and instead relying on the absence of reported adverse events to justify low residual risk scores. For example, in the General Product Report (b) (4) for Pulp Damage, your firm lists controls including (b) (4) (b) (4) to reduce risk from initial index of (b) (4) to final index of (b) (4) but no verification records were available showing:

- These controls were implemented in the product design, manufacturing process, or instructions for use
- Testing or validation demonstrating these controls are effective in preventing pulp damage
- How these specific controls reduce the risk index by (b) (4)

Additionally, the same pattern also applied to the following failure modes for Gingival Reaction, Allergic Reaction, and Physical Complications.

***DATES OF INSPECTION**

4/06/2026(Mon), 4/07/2026(Tue), 4/08/2026(Wed), 4/09/2026(Thu), 4/14/2026(Tue), 4/15/2026(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Marlo-Ian M Alintanahin, Investigator	X Marlo-Ian M Alintanahin Investigator Signed By: Marlo Ian M. Alintanahin -S Date Signed: 04-15-2026 13:34:18	4/15/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/6/2026-4/15/2026*
	FEI NUMBER 2022039

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

David V. Butler , President

FIRM NAME	STREET ADDRESS
Scientific Pharmaceuticals, Inc.	3221 Producer Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pomona, CA 91768-3916	Manufacturer

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Marlo-Ian M Alintanahin, Investigator

X Marlo-Ian M Alintanahin Investigator Signed By: Marlo Ian M. Alintanahin -S Date Signed: 04-15-2026 13:34:18

DATE ISSUED

4/15/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/6/2026-4/15/2026*
	FEI NUMBER 2022039

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David V. Butler , President

FIRM NAME	STREET ADDRESS
Scientific Pharmaceuticals, Inc.	3221 Producer Way
CITY, STATE, ZIP CODE, COUNTRY Pomona, CA 91768-3916	TYPE ESTABLISHMENT INSPECTED Manufacturer

Annotations to Observations

Observation 1: Under consideration

Observation 2: Under consideration

Observation 3: Under consideration

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Marlo-Ian M Alintanahin, Investigator X Marlo-Ian M Alintanahin Investigator Signed By: Marlo Ian M. Alintanahin -S Date Signed: 04-15-2026 13:34:18	4/15/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."