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	7/17/2023-7/24/2023* FEI NUMBER 3003059934

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kitty A. Hunter, President

FIRM NAME	STREET ADDRESS
Advanced Cosmetic Research Laboratories, Inc.	20550 Prairie St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chatsworth, CA 91311-6006	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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Quality System

OBSERVATION 1

Individuals responsible for supervising the manufacture, processing, packing and holding of a drug product lack the education, training and experience to perform their assigned functions in such a manner as to assure the drug product has the safety, identity, strength, quality and purity that it purports or is represented to possess.

Specifically, the quality control unit is not trained or qualified to perform GMP functions for this firm. See observations below.

OBSERVATION 2

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, investigations were not documented and conducted for out-of-specification (OOS) results. No OOS events were reported in your firm's OOS log; however, when reviewing records, the following OOS results were discovered:

a. (b) (4) , lot # (b) (4) , failed finished product assay testing (b) (4) times. When an OOS result was received, a different unit from the batch was tested. Retesting concluded after the (b) (4) failing unit. No investigation was performed for any of the (b) (4) OOSs.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Khoa Nathan V Tran, Investigator Rowena S Nguyen, Investigator	X Khoa Nathan V Tran Investigator Signed By: 2003026741 Date Signed: 07-24-2023 12:47:59	7/24/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	7/17/2023-7/24/2023* FEI NUMBER 3003059934

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kitty A. Hunter, President	
FIRM NAME Advanced Cosmetic Research Laboratories, Inc.	STREET ADDRESS 20550 Prairie St
CITY, STATE, ZIP CODE, COUNTRY Chatsworth, CA 91311-6006	TYPE ESTABLISHMENT INSPECTED Manufacturer

b. 4 out of 5 batch records reviewed had OOS assay, viscosity, and color results.

Product	Lot	Test	Specification	Result	Release Date	Distribution Date
(b) (4), finished product	(b) (4)	Assay	(b) (4) - (b) (4)	(b) (4)%, (b) (4)% (retest), (b) (4)% (retest)	03/28/2022	05/09/2022
(b) (4) Treatment, finished product	(b) (4)	Assay	(b) (4) - (b) (4)%	(b) (4)%	02/14/2022	03/01/2022
(b) (4) Treatment, bulk	(b) (4)	Assay	(b) (4) - (b) (4)%	(b) (4)%	02/14/2022	03/01/2022
(b) (4), bulk	(b) (4)	Viscosity (at (b) (4) C)	(b) (4)	(b) (4)	06/30/2023	Awaiting to be picked up by carrier
(b) (4), bulk (combined with lot # (b) (4))	(b) (4)	Color	(b) (4)	"Batch rework/adjustment for color to be brought into spec."	06/30/2023	Awaiting to be picked up by carrier
(b) (4), bulk	(b) (4)	Viscosity	(b) (4) (b) (4)%). (b) (4) after (b) (4) .	(b) (4)	07/05/2023	Awaiting to be picked up by carrier

b. Approximately 23 OOS (b) (4) and 4 OOS microbiological results were observed when reviewing the

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	7/17/2023-7/24/2023* FEI NUMBER 3003059934

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kitty A. Hunter, President	
FIRM NAME Advanced Cosmetic Research Laboratories, Inc.	STREET ADDRESS 20550 Prairie St
CITY, STATE, ZIP CODE, COUNTRY Chatsworth, CA 91311-6006	TYPE ESTABLISHMENT INSPECTED Manufacturer

2022-2023 (b) (4) system testing log. (b) (4) from the (b) (4) is used for drug manufacturing. The OOS results include:

(b) (4) Analysis Result Log 2022

Valve #	Date of Sampling	Test	Specification	Result
(b) (4)	03/01/2022	(b) (4) at (b) (4) C	(b) (4) to (b) (4)	(b) (4) @ (b) (4) °C
	03/01/2022	at C	to	@ °C
	03/01/2022	at C	to	@ °C
	07/12/2022	at C	to	@ °C
	07/12/2022	at C	to	@ °C
	08/16/2022	at C	to	@ °C
	08/16/2022	at C	to	@ °C
	08/16/2022	at C	to	@ °C
	10/18/2022	at C	to	(b) (4) @ (b) (4) °C
	10/18/2022	at C	to	@ °C

(b) (4) Analysis Result Log 2023

Valve #	Date of Sampling	Test	Specification	ACRL Result	Contract Lab Result
(b) (4)	04/11/2023	Total Plate Count	(b) (4) CFU (b) (4) ml	163 CFU/(b) (4) ml	(b) (4) /1ml ((b) (4) /(b) (4) ml)
	06/06/2023	Total Plate Count	(b) (4) CFU/(b) (4) ml	(b) (4) CFU/(b) (4) ml	(b) (4) /1ml ((b) (4) /(b) (4) ml)
	06/27/2023	Total	(b) (4)	(b) (4)	(b) (4) /1ml

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Khoa Nathan V Tran, Investigator
Rowena S Nguyen, Investigator

X Khoa Nathan V Tran
Investigator
Signed By: 2003026741
Date Signed: 07-24-2023
12:47:59

DATE ISSUED
7/24/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	7/17/2023-7/24/2023* FEI NUMBER 3003059934

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kitty A. Hunter, President

FIRM NAME	STREET ADDRESS
Advanced Cosmetic Research Laboratories, Inc.	20550 Prairie St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chatsworth, CA 91311-6006	Manufacturer

		Plate Count	CFU/(b) (4)ml	CFU/(b) (4)ml	((b) (4)/(b) (4)ml)
(b) (4)	06/27/2023	Total Plate Count	(b) (4) CFU/(b) (4)ml	(b) (4) CFU/(b) (4)ml	(b) (4)/1ml ((b) (4)/(b) (4)ml)

OBSERVATION 3

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically, most batch records were reviewed and approved before the completion of batch production. 3 of 5 batch records reviewed showed approvals before completion of filling. For example:

Product/Lot #	Release Date	Fill Date
(b) (4) , lot # (b) (4)	07/05/2023	07/05 - 06/2023
(b) (4) Treatment, lot # (b) (4)	2/14/2022	02/14 - 17/2022
(b) (4) , lot # (b) (4)	03/28/2022	03/29 - 30/2022

Additionally, failing test results were received after batch records were reviewed and approved. For example:

Product/Lot #	Release Date	Failure
(b) (4) , lot # (b) (4)	3/28/22	(b) (4) assay failure results received

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Khoa Nathan V Tran, Investigator
Rowena S Nguyen, Investigator

X Khoa Nathan V Tran
Investigator
Signed By: 2003026741
Date Signed: 07-24-2023
12:47:59

DATE ISSUED
7/24/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	7/17/2023-7/24/2023* FEI NUMBER 3003059934

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kitty A. Hunter, President	
FIRM NAME Advanced Cosmetic Research Laboratories, Inc.	STREET ADDRESS 20550 Prairie St
CITY, STATE, ZIP CODE, COUNTRY Chatsworth, CA 91311-6006	TYPE ESTABLISHMENT INSPECTED Manufacturer

		4/11/22, 4/15/22, 5/2/22
(b) (4) Treatment, lot # (b) (4)	2/14/22	Assay failure result received 2/22/22
(b) (4) Treatment (bulk), lot # (b) (4)	2/11/22 (for filling)	Bulk assay failure result received 2/22/22

Facilities and Equipment System

OBSERVATION 4

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, your firm has not performed cleaning validation of (b) (4) tanks and (b) (4) totes to assure unacceptable carryover from batch to batch. Your (b) (4) tanks and (b) (4) totes are not dedicated for specific products and are used for the manufacture and holding of drug products and cosmetic products.

OBSERVATION 5

Buildings used in the manufacturing, processing, packing and holding of a drug product are not maintained in a good state of repair.

Specifically,

a. Pipes directly above (b) (4) tanks had apparent rust and dirt, thereby potentially contaminating the (b) (4) tanks with debris.

b. Aluminum sheet panels were observed separating from the ceiling in the raw material weighing area, production area, raw material storage area, staged material storage area, released bulk storage area, packaging component storage area, and receiving/quarantine area - exposing areas above.

c. An electrical cord above the (b) (4) tanks had apparent dust and dirt, thereby potentially contaminating the (b) (4) tanks with debris.

d. On 07/17/2023, water was observed dripping from a platform onto a (b) (4) tank below. Other (b) (4) tanks were being stored and used under this platform.

This is a repeat observation from the Aril 2022 FDA inspection.

Production System

OBSERVATION 6

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

a. Process validation has not been performed for any drug products, including (b) (4), (b) (4) (b) (4) Treatment, (b) (4), (b) (4), and (b) (4) SPF-30. Furthermore,

1. Assay, viscosity, and color out-of specification results were received during drug production.
2. (b) (4), lot # (b) (4), was reworked by combining old bulk ((b) (4), lot # (b) (4)) with new bulk ((b) (4), lot # (b) (4)) to fulfill an order's quantity

requirement. Lot # (b) (4) was compounded 02/25/2022. The two lots were combined 06/29/2023.

b. Your (b) (4) system has not been qualified to meet USP (b) (4) standards. TOC testing has not been performed. Conductivity testing is not performed according to USP. Drug products are manufactured using this (b) (4). For example, "(b) (4) ", lot # (b) (4) , was used to manufacture (b) (4) (b) (4), lot # (b) (4) .

Materials System

OBSERVATION 7

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically, full testing against the supplier's COA has not been performed for any drug component. Additionally, supplier qualification has not been performed for any of your drug component suppliers.

OBSERVATION 8

Drug product component testing is deficient in that at least one specific test to verify the identity of each component is not performed.

Specifically, complete identity testing has not been conducted for all lots of (b) (4) and (b) (4) (b) (4) as (b) (4) % and (b) (4) % have not been tested. Your firm has received approximately (b) (4) lots of (b) (4) and (b) (4) lots of (b) (4) since 2022. (b) (4) , lot # (b) (4) , was used to manufacture (b) (4) , lot # (b) (4) .

Laboratory System

OBSERVATION 9

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	7/17/2023-7/24/2023* FEI NUMBER 3003059934

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kitty A. Hunter, President	
FIRM NAME	STREET ADDRESS
Advanced Cosmetic Research Laboratories, Inc.	20550 Prairie St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chatsworth, CA 91311-6006	Manufacturer

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically, laboratory analysts have the ability to delete (b) (4) data. The (b) (4) computerized system is used to test and release incoming drug components. For example, the (b) (4) was used to test and release active pharmaceutical ingredient (b) (4), lot # (b) (4), for the production of (b) (4), lot # (b) (4). Moreover, there is no audit trail control to detect the deletion of data.

***DATES OF INSPECTION**

7/17/2023(Mon), 7/18/2023(Tue), 7/19/2023(Wed), 7/20/2023(Thu), 7/21/2023(Fri), 7/24/2023(Mon)

X Rowena S Nguyen
Investigator
Signed By: Rowena S. Nguyen -S
Date Signed: 07-24-2023 12:48:45

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Khoa Nathan V Tran, Investigator Rowena S Nguyen, Investigator	X Khoa Nathan V Tran Investigator Signed By: 2003026741 Date Signed: 07-24-2023 12:47:59	7/24/2023

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."