BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

AVANIR PHARMACEUTICALS, INC., dba AVANIR PHARMACEUTICALS INC., Original Wholesale Permit No. WLS 5558;

AVANIR PHARMACEUTICALS, INC., dba AVANIR PHARMACEUTICALS INC., Original Wholesale Permit No. WLS 6793;

and

AVANIR PHARMACEUTICALS, INC., dba AVANIR PHARMACEUTICALS INC., Original Wholesale Permit No. WLS 7732,

Respondents.

Agency Case No. 7598

DECISION AND ORDER

The attached Stipulated Surrender of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on July 18, 2024.

It is so ORDERED on June 18, 2024.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Seung W. Oh, Pharm.D. Board President

1	ROB BONTA		
2	Attorney General of California MARICHELLE S. TAHIMIC		
3	Supervising Deputy Attorney General DIONNE MOCHON		
4	Deputy Attorney General State Bar No. 203092		
5	600 West Broadway, Suite 1800 San Diego, CA 92101		
6	P.O. Box 85266 San Diego, CA 92186-5266		
7	Telephone: (619) 738-9012 Facsimile: (619) 645-2061		
8	Attorneys for Complainant		
9	BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS		
0			
1		CALIFORNIA	
2	In the Matter of the Accusation Against:	Case No. 7598	
.3	AVANIR PHARMACEUTICALS, INC. DBA AVANIR PHARMACEUTICALS	STIPULATED SURRENDER OF	
4	INC.	LICENSE AND ORDER	
5	Original Wholesale Permit No. WLS 5558		
6	30 Enterprise, Suite 400 Aliso Viejo, CA 92656		
7	AVANIR PHARMACEUTICALS, INC.		
8	DBA AVANIR PHARMACEUTICALS INC.		
9	Original Wholesale Permit No. WLS 6793		
0	30 Enterprise, Suite 400		
1	Aliso Viejo, CA 92656		
2	AVANIR PHARMACEUTICALS, INC.		
3	DBA AVANIR PHARMACEUTICALS INC.		
4			
5	Original Wholesale Permit No. WLS 7732		
6	30 Enterprise, Suite 200 Aliso Viejo, CA 92656		
7	Respondent		
8			

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the aboveentitled proceedings that the following matters are true:

PARTIES

- 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Dionne Mochon, Deputy Attorney General.
- 2. Respondent Avanir Pharmaceuticals Inc. (Respondent) dba Avanir Pharmaceuticals, Inc. is represented in this proceeding by attorney Daniel Guggenheim, whose address is Quarles and Bardy, LLP, 101 W. Broadway, Ninth Floor, San Diego, California, 92101.
- 3. On or about April 21, 2010, the Board issued Original Wholesale Permit Number WLS 5558 to Respondent to do business as Avanir Pharmaceuticals, Inc. The Original Wholesale Permit expired on May 24, 2016 pursuant to a change of ownership.
- 4. On or about May 23, 2016, the Board issued Original Wholesale Permit Number WLS 6793 to Respondent to do business as Avanir Pharmaceuticals, Inc. The Original Wholesale Permit expired on March 30, 2020 pursuant to a change in location, as reflected in paragraph 4, below.
- 5. On or about March 30, 2020, the Board issued Original Wholesale Permit Number WLS 7732 to Respondent to do business as Avanir Pharmaceuticals, Inc. located at 30 Enterprise, Suite 200, Aliso Viejo, CA 92656. The Wholesale Permit expired on January 1, 2023 pursuant to Discontinuance of Business.

JURISDICTION

6. Accusation No. 7598 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on December 8, 2023. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 7598 is attached as Exhibit A and incorporated by reference.

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ADVISEMENT AND WAIVERS

- 7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7598. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.
- 8. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.
- 9. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- 10. Respondent admits the truth of each and every charge and allegation in Accusation No. 7598, agrees that cause exists for discipline and hereby surrenders its Original Wholesale Permit No. WLS 5558 for the Board's formal acceptance.
- 11. Respondent admits the truth of each and every charge and allegation in Accusation No. 7598, agrees that cause exists for discipline and hereby surrenders its Original Wholesale Permit No. WLS 6793 for the Board's formal acceptance.
- 12. Respondent admits the truth of each and every charge and allegation in Accusation No. 7598, agrees that cause exists for discipline and hereby surrenders its Original Wholesale Permit No. WLS 7732 for the Board's formal acceptance
- 13. Respondent understands that by signing this stipulation, it enables the Board to issue an order accepting the surrender of its Original Wholesale Permits without further process.

CONTINGENCY

14. This stipulation shall be subject to approval by the Board. Respondent understands and agrees that counsel for Complainant and the staff of the Board may communicate directly

with the Board regarding this stipulation and surrender, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

- 15. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.
- 16. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 17. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Wholesale Permit No. WLS 5558, Original Wholesale Permit No. WLS 6793, and Original Wholesale Permit No. WLS 7732 issued to Respondent Avanir Pharmaceuticals, Inc., are surrendered and accepted by the Board.

1. The surrender of Respondent's Original Wholesale Permit 5558, Original Wholesale Permit 6793, and Original Wholesale Permit 7732 and the acceptance of the surrendered licenses by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board. Respondent understands and agrees that for purposes of Business and Professions Code section 4307, the surrender shall be construed the same as revocation.

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- 2. Respondent shall lose all rights and privileges as a wholesaler in California as of the effective date of the Board's Decision and Order.
- 3. Respondent shall cause to be delivered to the Board its pocket licenses and, if one was issued, its wall certificates on or before the effective date of the Decision and Order.
- 4. Respondent may not apply for any license, permit, or registration from the Board for three years from the effective date of this decision. If Respondent ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Accusation No. 7598 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.
- 5. Respondent shall pay the agency its costs of investigation and enforcement in the amount of \$5,543.75 prior to issuance of a new or reinstated license.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney Doug Ottenwess, Esq. I understand the stipulation and the effect it will have on my Original Wholesale Permits. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 25-Apr-2024 | 13:31 PDT

— Docusigned by: Lowis Allesandrine

LOUIS ALLESANDRINE, as President and an authorized agent on behalf of AVANIR PHARMACEUTICALS, INC. Respondent

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1	I have read and fully discussed with Respondent Avanir Pharmaceuticals, Inc. the terms	and			
2	conditions and other matters contained in this Stipulated Surrender of License and Order. I				
3	approve its form and content.				
4	DATED:				
5	DANIEL GUGGENHEIM, ESQ. Attorney for Respondent				
6					
7	<u>ENDORSEMENT</u>				
8	The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted				
9	for consideration by the Board of Pharmacy of the Department of Consumer Affairs.				
10	DATED: Respectfully submitted,				
11	ROB BONTA Attorney General of California				
12	MARICHELLE S. TAHIMIC Supervising Deputy Attorney General				
13	Supervising Deputy Attorney General				
14					
15	DIONNE MOCHON Deputy Attorney General Attorneys for Complainant				
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1	I have read and fully discussed with Respondent Avanir Pharmaceuticals, Inc. the terms and
2	conditions and other matters contained in this Stipulated Surrender of License and Order. I
3	approve its form and content.
4	DATED: 4/29/2024 Pariel Jugenheim
5	DANIEL GUGGENHEIM, ESQ. Attorney for Respondent
6	in the state of th
	ENDORSEMENT
7 8	The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted
9	for consideration by the Board of Pharmacy of the Department of Consumer Affairs.
10	DATED: 04/30/2024 Respectfully submitted,
11	ROB BONTA Attorney General of California
12	MARICHELLE S. TAHIMIC Supervising Deputy Attorney General
13	
14	DIONNE MOCHON
15	Dionne Mochon Deputy Attorney General Attorneys for Complainant
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Exhibit A

Accusation No. 7598

1	ROB BONTA		
2	Attorney General of California		
	MARICHELLE S. TAHIMIC Supervising Deputy Attorney General		
3	DIONNE MOCHON Deputy Attorney General		
4	State Bar No. 203092 600 West Broadway, Suite 1800		
5	San Diego, CA 92101 P.O. Box 85266		
6	San Diego, CA 92186-5266 Telephone: (619) 738-9012		
7	Facsimile: (619) 645-2061 Attorneys for Complainant		
8			
9	BEFORE THE		
10	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS		
11	STATE OF CA	LIFORNIA	
12	In the Matter of the Accusation Against:	Case No. 7598	
13	AVANIR PHARMACEUTICALS, INC. DBA AVANIR PHARMACEUTICALS INC.		
14	Original Wholesale Permit No. WLS 5558	ACCUSATION	
15	30 Enterprise, Suite 400		
16	Aliso Viejo, CA 92656		
17	AVANIR PHARMACEUTICALS, INC. DBA AVANIR PHARMACEUTICALS INC.		
18	Original Wholesale Permit No. WLS 6793		
19	30 Enterprise, Suite 400		
20	Aliso Viejo, CA 92656		
21	AVANIR PHARMACEUTICALS, INC.		
22	DBA AVANIR PHARMACEUTIČALS INC.		
23	Original Wholesale Permit No. WLS 7732		
24	30 Enterprise, Suite 200		
25	Aliso Viejo, CA 92656		
26	Respondent.		
27			
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(AVANIR PHARMACEUTICALS, INC.) ACCUSATION

PARTIES

- 1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.
- 2. On or about April 21, 2010, the Board issued Original Wholesale Permit Number WLS 5558 to Avanir Pharmaceuticals Inc. (Respondent) to do business as Avanir Pharmaceuticals, Inc. The Original Wholesale Permit expired on May 24, 2016 pursuant to a change of ownership.
- 3. On or about May 23, 2016, the Board issued Original Wholesale Permit Number WLS 6793 to Respondent to do business as Avanir Pharmaceuticals, Inc. The Original Wholesale Permit expired on March 30, 2020 pursuant to a change in location, as reflected in paragraph 4, below.
- 4. On or about March 30, 2020, the Board issued Original Wholesale Permit Number WLS 7732 to Respondent to do business as Avanir Pharmaceuticals, Inc. located at 30 Enterprise, Suite 200, Aliso Viejo, CA 92656. The Wholesale Permit expired on January 1, 2023 pursuant to Discontinuance of Business.

JURISDICTION AND STATUTORY PROVISIONS

- 5. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.
- 6. Section 118, subdivision (b) of the Code, provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.
 - 7. Section 493 of the Code states:

Notwithstanding any other provision of law, in a proceeding conducted by a board within the department pursuant to law to deny an application for a license or to suspend or revoke a license or otherwise take disciplinary action against a person who holds a license, upon the ground that the applicant or the licensee has been convicted of a crime substantially related to the qualifications, functions, and duties of the licensee in question, the record of conviction of the crime shall be conclusive evidence of the fact that the conviction occurred, but only of that fact, and the board

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1 2	may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, and duties of the licensee in question.			
3	As used in this section, 'license' includes 'certificate,' 'permit,' 'authority,' and 'registration.'			
4	8. Section 4011 of the Code provides that the Board shall administer and enforce both			
5	the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances			
6	Act [Health & Safety Code, § 11000 et seq.].			
7	9. Section 4022.5 of the Code states:			
8	(a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section			
9	4053 shall not be required to obtain a license as a designated representative.			
10	10 0 4 4052 64 6 1 44			
11	10. Section 4053 of the Code states:			
12 13	(a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the			
14	public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.			
15				
16	11. Section 4300 of the Code states in pertinent part:			
17	(a) of the Code provides that every license issued by the Board may be suspended or revoked.			
18				
19	(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:			
20	(1) Suspending judgment.			
21	(2) Placing him or her upon probation.			
22	(3) Suspending his or her right to practice for a period not exceeding one year.			
23	(4) Revoking his or her license.			
24	(5) Taking any other action in relation to disciplining him or her as the board in			
25	its discretion may deem proper.			
26				
27	(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the			
28	Government Code, and the board shall have all the powers granted therein. The			

any other position with management or control of a licensee as follows:

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marketing of Nuedexta®. As part of the settlement, Respondent entered into a Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General for five years. On December 25, 2019, the court filed a Joint Stipulation of Dismissal based upon the executed settlement.

Criminal Charges Filed Alleging Payment of Kickbacks

- 18. On or about September 26, 2019, the United States Attorney's Office filed a criminal information in the U.S. District Court, Northern District of Georgia, Case No. 1:19-CR-22369, charging Respondent with paying kickbacks to a physician to prescribe Nuedxta® to federal healthcare program beneficiaries and to recommend that other physicians prescribe the drug as well.
- 19. The criminal information alleged that between at least November 2011 through February 2016, Respondent paid a physician more than \$330,000.00 in speaker fees and honoraria. Federal programs such as Medicare and Medicaid paid over \$5,000,000.00 for prescriptions obtained as part of the kickback scheme. Members of Respondent's sales and marketing management concealed communications about the kickback scheme, including detection by the company's compliance department, by using encrypted and anonymous messaging applications and encouraging deletion of incriminating texts and emails.
- 20. On September 26, 2019, Respondent entered into a three year deferred prosecution agreement and agreed to pay \$12,874,895.00 in criminal penalties and forfeitures. On November 30, 2022, the court dismissed the criminal information with prejudice based on the expiration of the deferred prosecution agreement.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit)

21. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (f), in that between at least October 29, 2010 through December 31, 2016, Respondent provided illegal kickbacks to physicians and health care professionals to induce physicians to prescribe Nuedexta®, as more fully alleged and set forth in paragraphs 16 through 20 and incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Falsifying Documents)

22. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivisions (f) and (g), in that between at least October 29, 2010 through December 31, 2016, Respondent knowingly made or signed documents that falsely represented the existence or nonexistence of a state of facts by submitting kickbacks to a physician in exchange for increased prescriptions to enrollees in federal programs such as Medicare and Medicaid, and by agreeing to a separate civil resolution with the Department of Justice to resolve allegations under the False Claims Act, as more fully alleged and set forth in paragraphs 16 through 20 and incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Violation of Statutes Regulating Controlled Substances)

23. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (j), in that between at least October 29, 2010 through December 31, 2016, Respondent violated California statutes and/or federal state laws regulating controlled substances and dangerous drugs, as more fully alleged and set forth in paragraphs 16 through 20 and incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Violating California Statutes Applicable to Pharmacy)

24. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), in that between at least October 29, 2010 through December 31, 2016, Respondent violated California statutes and regulations, and/or federal laws governing pharmacy, as more fully alleged and set forth in paragraphs 16 through 20 and incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Acts Warranting Denial of Licensure)

25. Respondent is subject to disciplinary action pursuant to section 4301, subdivisions (p), on the grounds of unprofessional conduct in that Respondent committed acts violating

Pharmacy Law and/or federal and state laws governing pharmacy that would have warranted denial of a license, as more fully alleged and set forth in paragraphs 16 through 20 and incorporated herein by reference.

DISCIPLINE CONSIDERATIONS

26. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges that on or about September 3, 2019, in a prior action, the Board of Pharmacy issued Citation Number CI 2019 85221 to Respondent against Pharmacy Permit Number WLS 6793. The Citation was issued to Respondent for violation of Code section 4305.5, subdivision (a), for failure to notify the Board within thirty days of the termination of employment of the designated representative in charge. The Board issued a fine of \$1,000.00. That Citation is now final.

OTHER MATTERS

27. Pursuant to Code section 4307, if discipline is imposed on Original Wholesale Permit Numbers WLS 5558, WLS 6793, or WLS 7732, issued to Avanir Pharmaceuticals Inc. doing business as Avanir Pharmaceuticals, Inc. then Avanir Pharmacuticals Inc., shall be prohibited from serving as manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years, if Original Wholesale Permit NumbersWLS 5558, WLS 6793, or WLS 7732 is placed on probation, or if it is revoked, until Original Wholesale Permit Numbers WLS 5558, WLS 6793, or WLS 7732 is reinstated.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- 1. Revoking or suspending Original Wholesale Permit Number WLS 5558, issued to Avanir Pharmaceuticals, Inc.;
- 2. Revoking or suspending Original Wholesale Permit Number WLS 6793, issued to Avanir Pharmaceuticals, Inc.;
- 3. Revoking or suspending Original Wholesale Permit Number WLS 7732, issued to Avanir Pharmaceuticals, Inc.;

(AVANIR PHARMACEUTICALS, INC.) ACCUSATION