UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES EXCHANGE ACT OF 1934
Release No. 77431 / March 23, 2016

ACCOUNTING AND AUDITING ENFORCEMENT
Release No. 3759 / March 23, 2016

ADMINISTRATIVE PROCEEDING
File No. 3-17177

In the Matter of **NOVARTIS AG,** **Respondent.**	**ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS PURSUANT TO SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, MAKING FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER**

I.

The Securities and Exchange Commission ("Commission") deems it appropriate and in the public interest that public administrative and cease-and-desist proceedings be, and hereby are, instituted pursuant to 21C of the Securities Exchange Act of 1934 ("Exchange Act") against Novartis AG ("Novartis" or "Respondent").

II.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the "Offer") which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission's jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order ("Order"), as set forth below.

III.

On the basis of this Order and Respondent's Offer, the Commission finds[1] that:

1. These proceedings arise out of violations of the books and records and internal accounting controls provisions of the Foreign Corrupt Practices Act of 1977 (the "FCPA") by respondent Novartis AG ("Novartis") concerning its pharmaceutical operations in China.

2. From at least 2009 to 2013, certain employees and agents of Novartis subsidiaries conducting business in China engaged in transactions and provided things of value to foreign officials, principally healthcare professionals ("HCPs"). These payments took varied forms and were intended to influence the HCPs and thereby increase sales of Novartis pharmaceutical products. Employees and managers in the involved subsidiaries attempted to conceal the true nature of the transactions through the use of complicit third parties and by improperly recording the relevant transactions on the books and records of the respective subsidiaries, which were consolidated in the financial reports of Novartis. Examples include improperly recording the payments as legitimate expenses for travel and entertainment, conferences, lecture fees, marketing events, educational seminars, and medical studies. Novartis also failed to devise and maintain an effective system of internal accounting controls or an effective anti-corruption compliance program.

3. As a result of this conduct, perpetrated by employees and agents of Novartis subsidiaries in China, Novartis violated Section 13(b)(2)(A) of the Securities Exchange Act of 1934 ("Exchange Act") by failing to make and keep books, records and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and disposition of assets of the issuer. Additionally, Novartis violated Section 13(b)(2)(B) of the Exchange Act, as it failed to maintain a system of internal accounting controls sufficient to provide reasonable assurances that within the China subsidiaries: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements; (iii) transactions are recorded as necessary to maintain accountability for assets; and (iv) that access to assets is permitted only in accordance with management's general or specific authorization.

Respondent

4. **Novartis AG** ("Novartis") is a corporation organized under the laws of Switzerland. Novartis' headquarters are located in Basel, Switzerland. Novartis issued and maintains a class of publicly traded securities registered pursuant to Section 12(b) of the

[1] The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

Securities Exchange Act of 1934, which are traded on the New York Stock Exchange.

5. Novartis is a global provider of pharmaceutical and over-the-counter health products. Novartis' products are available in 180 countries and Novartis employs approximately 120,000 employees. Novartis manages its operations by therapeutic area. Novartis conducts business in China solely through its subsidiaries, including the two subsidiaries identified below.

Other Relevant Entities

6. **Shanghai Novartis Trading Ltd** ("Sandoz China") is headquartered in Shanghai, China. Among other things, Sandoz China conducts the sales and marketing activities of Novartis generic pharmaceutical products in China including Sandostatin. Sandoz China is an indirect subsidiary of Novartis.

7. **Beijing Novartis Pharma Co, Ltd** ("Novartis China") is based in Beijing, China. Among other things, Novartis China conducts the broader operations for Novartis AG in China including the sale and marketing of proprietary pharmaceutical products. Novartis China is an indirect subsidiary of Novartis.

Sandoz China

8. Between 2009 and 2011, certain employees of Novartis' subsidiary, Sandoz China, improperly provided things of value to HCPs in China in connection with pharmaceutical sales and involved certain complicit managers. The things of value took varied forms, and included gifts, travel, improper sightseeing or vacations, entertainment, and favors for families of HCPs. These things of value were improperly recorded on the general ledger as legitimate employee expenses, sponsorships, conferences, medical studies, and marketing costs.

9. Certain sales representatives of Sandoz China reported to their managers the results of their efforts to increase the sales volume of various generic products. High prescribing HCPs were referred to as "key" customers and the volume of their prescriptions was reported to certain senior management at Sandoz China. In order to influence HCPs, certain sales representatives provided HCPs with such things as cash and gifts, which were funded through the submission of false expense reports. This practice was known to certain members of management of Sandoz China, including certain area and district managers and the country sales supervisor. For example, in 2011, two sales representatives submitted fake receipts for approximately $8,100 as part of their employee expense reimbursement requests, which were approved by a regional sales manager. The proceeds were used to entertain and provide gifts to HCPs. In one instance, a sales representative submitted a fake $1,154 receipt to purchase holiday gifts for 25 HCPs when the proceeds were actually used to pay for spa and sauna sessions for HCPs. A regional sales manager approved the purchase.

10. In connection with this practice, certain employees maintained projections in spreadsheets that directly linked a certain cash value to be provided to HCPs in exchange for a certain number of prescriptions per month. In certain instances, these planned amounts were referred to as "investments," between several hundred and several thousand dollars annually, and the HCPs were in some instances categorized into and tracked by different tiers, including one tier described as "money worshippers."

11. As part of its normal business operations, Sandoz China hired local Chinese travel companies to arrange transportation, accommodations, and meals for HCPs in connection with education events. However, in many instances, the actual trips did not include an educational purpose or the scientific/educational components were minimal in comparison to the sightseeing or recreational activities, and were instead a method of influencing the HCPs. The related expenses were approved and paid with little or no supporting documentation. For example:

- In 2009, Sandoz China sponsored twenty Chinese HCPs to attend the American College of Surgeons 95th Annual Clinical Congress in Chicago. While the Clinical Congress was devoted to educational purposes, the HCPs were also provided purely sightseeing or recreational activities, such as an excursion to Niagara Falls. Sandoz China also paid for travel to the U.S. for spouses of the HCPs, $150 in "pocket" or "walking around" money, and cover charges at a strip club. A senior manager of Sandoz China and other Sandoz China employees accompanied the HCPs to Chicago.

- In 2011, a Chinese travel company submitted several invoices totaling approximately $25,000 ostensibly in connection with lectures by an HCP to other HCPs. The invoices were paid and recorded as legitimate expenses despite the lack of any confirmation: (1) that the lecture was organized by Sandoz China and held in the venue for which an invoice was submitted; and (2) that the lecture was attended by HCPs.

12. Sandoz China used other methods to provide monies to HCPs. In 2009 and 2010, Sandoz China paid HCPs to collect and analyze patient medical data for the stated purpose of better understanding the use and reaction of a particular Novartis drug among patients. Senior levels of the Sandoz China sales and marketing team were involved in the design and execution of the studies.

13. In reality, the studies did not provide any legitimate medical data, but rather were used to financially reward HCPs who had prescribed the drug. The studies were not approved by the Novartis Global Clinical Quality Assurance group, as policy required, and the

studies did not collect or analyze substantive patient data regarding the drug. Despite the lack of real scientific data, payments of approximately $88-135 per data submission were made to the prescribing HCPs. The payments made to HCPs under these studies totaled approximately $522,000 between 2009 and 2010.

Novartis China

14. Between 2011 and 2013, employees and agents of Novartis China made payments to government officials in China in connection with pharmaceutical sales. The payments were made through event planning and travel companies retained by Novartis China ostensibly to arrange transportation, accommodations and meals for HCPs in connection with educational conferences and other business activities. Through the use of these complicit vendors, HCPs were provided with improper inducements to prescribe or recommend Novartis products. The subsidiary recorded these payments as legitimate selling and marketing costs in its books.

15. Novartis China retained numerous third-party travel and event planning vendors to organize and manage marketing for HCPs events, both locally within China, and outside China. The range of services varied but in some cases vendors arranged the venue, food, entertainment, flights, hotels, and transit depending upon the location of the event and number of participants. In the past several years, Novartis China has hosted thousands of such events, and the pharmaceutical business unit within Novartis China was the largest consumer of these services.

16. Despite the widespread use of third-party travel and event planning vendors in China, Novartis did not have sufficient internal accounting controls or anti-corruption compliance measures in connection with the use of these vendors. Among other things, Novartis failed to conduct sufficient training of its sales staff and managers to prevent and detect inappropriate payments made to and/or through these vendors, failed to conduct proper due diligence in connection with these vendors and failed to ensure sufficient and appropriate support for the selling and marketing expenses submitted by these vendors.

Novartis' Cooperation and Remediation

17. In connection with the SEC Staff s investigation and in response to media reports concerning a competitor in August 2013, Novartis instituted an expansive review of its relationships in China with travel and event planning vendors. Novartis' internal review showed that the vast majority of these vendors were retained in connection with events in which HCPs attended. It also identified a significant percentage of events that did not comply with existing Novartis Corporate policies and procedures. This included events for which no record existed to verify it had occurred, events for which inconsistent records existed, and events that could not be verified from available information. Through this mechanism of using travel agencies and similar vendors to plan events, funds were generated that were used to provide improper payments and other inducements to HCPs in order to increase sales of Novartis

products.

18. As a result of its internal review over relationships with local Chinese third-party travel and event planning vendors, Novartis identified weaknesses in its internal controls over third party relationships at Novartis China. Novartis promptly took remedial steps to improve its internal controls at Novartis China including overhauling its anti-corruption policies and procedures, terminating and/or imposing other disciplinary sanctions against culpable employees, suspending vendor relationships and payments, doubling its training initiatives, re-organized its compliance function to include enhanced oversight by regional and headquarter compliance personnel, and eliminated the use of vendors to support external meetings.

Legal Standards and Violations

Under Section 21C(a) of the Exchange Act, the Commission may impose a cease-and-desist order upon any person who is violating, has violated, or is about to violate any provision of the Exchange Act or any rule or regulation thereunder, and upon any other person that is, was, or would be a cause of the violation, due to an act of omission the person knew or should have known would contribute to such violation.

FCPA Violations

Under Section 13(b)(2)(A) of the Exchange Act issuers are required to make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and disposition of the assets of the issuer. [15 U.S.C. § 78m(b)(2)(A)].

Under Section 13(b)(2)(B) of the Exchange Act issuers are required to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary (I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and (II) to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. [15 U.S.C. § 78m(b)(2)(B)].

As described above, Novartis violated Section 13(b)(2)(A) of the Exchange Act by improperly recording the payments to health care providers as sales, marketing, and promotion expenses. The false entries were initially recorded by Sandoz China and Novartis China which were then consolidated and reported by Novartis in its consolidated financial statements. Novartis violated Section 13(b)(2)(B) by failing to devise and maintain sufficient accounting controls to detect and prevent the making of improper payments to foreign officials.

Undertakings

Respondent has undertaken to:

1. Report to the Commission staff periodically, at no less than nine-month intervals during a two-year term, the status of its remediation and implementation of compliance measures. During this two-year period, should Respondent discover credible evidence, not already reported to the Commission staff, that questionable or corrupt payments or questionable or corrupt transfers of value may have been offered, promised, paid, or authorized by Respondent, or any entity or person acting on behalf of Respondent, or that related false books and records have been maintained, Respondent shall promptly report such conduct to the Commission staff. During this two-year period, Respondent shall: (1) conduct an initial review and submit an initial report, and (2) conduct and prepare at least two follow-up reviews and reports, as described below:

   a. Respondent shall submit to the Commission staff a written report within 180 calendar days of the entry of this Order setting forth a complete description of its Foreign Corrupt Practices Act ("FCPA") and anti-corruption related remediation efforts to date, its proposals reasonably designed to improve the policies and procedures of Respondent for ensuring compliance with the FCPA and other applicable anticorruption laws, and the parameters of the subsequent reviews (the "Initial Report"). The Initial Report shall be transmitted to Charles Cain, Deputy Unit Chief, FCPA Unit, Division of Enforcement, United States Securities and Exchange Commission, 100 F St NE, Washington, DC 20549. Respondent may extend the time period for issuance of the Initial Report with prior written approval of the Commission staff.

   b. Respondent shall undertake at least two follow-up reviews, incorporating any comments provided by the Commission staff on the previous report, to further monitor and assess whether the policies and procedures of Respondent are reasonably designed to detect and prevent violations of the FCPA and other applicable anti-corruption laws (the "Follow-up Reports").

   c. The first Follow-up Report shall be completed by no later

than 270 days after the Initial Report. The second Follow-up Report shall be completed by no later than 450 days after the completion of the Initial Report. Respondent may extend the time period for issuance of the Follow-up Reports with prior written approval of the Commission staff.

d. The periodic reviews and reports submitted by Respondent will likely include proprietary, financial, confidential, and competitive business information. Public disclosure of the reports could discourage cooperation, impede pending or potential government investigations and thus undermine the objectives of the reporting requirement. For these reasons, among others, the reports and the contents thereof are intended to remain and shall remain non-public, except (a) pursuant to court order, (b) as agreed by the parties in writing, (c) to the extent that the Commission staff determines in its sole discretion that disclosure would be in furtherance of the Commission's discharge of its duties and responsibilities, or (d) is otherwise required by law.

2. Certify, in writing, compliance with the undertaking(s) set forth above. The certification shall identify the undertaking(s) provide written evidence of compliance in the form of a narrative, and be supported by exhibits sufficient to demonstrate compliance. The Commission staff may make reasonable requests for further evidence of compliance, and Respondent agrees to provide such evidence. The certification and supporting materials shall be submitted to Charles Cain, Deputy Unit Chief, FCPA Unit, with a copy to the Office of the Chief Counsel of the Enforcement Division, no later than sixty (60) days from the date of the completion of the undertakings.

IV.

In view of the foregoing, the Commission deems it appropriate to impose the sanctions agreed to in Respondent Novartis' Offer.

Accordingly, pursuant to 21C of the Exchange Act, it is hereby ORDERED that:

A. Respondent Novartis cease and desist from committing or causing any violations and any future violations of Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act;

B. Respondent shall, within 14 days of the entry of this Order, pay disgorgement, of $21,579,217 and prejudgment interest of $1,470,887 to the Securities and Exchange Commission

for transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment of disgorgement or prejudgment interest is not made, additional interest shall accrue pursuant to SEC Rule of Practice 600. Respondent shall, within 14 days of the entry of this Order, pay a civil money penalty in the amount of $2,000,000 to the Securities and Exchange Commission for transfer to the general fund of the United States Treasury, subject to Exchange Act Section 21F(g)(3). If timely payment of civil money penalty is not made, additional interest shall accrue pursuant to 31 U.S.C. 3717. Payment must be made in one of the following ways:

(1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;

(2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at http://www.sec.gov/about/offices/ofm.htm; or

(3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center
Accounts Receivable Branch
HQ Bldg., Room 181, AMZ-341
6500 South MacArthur Boulevard
Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying Novartis as a Respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to Charles Cain, Deputy Unit Chief, FCPA Unit, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Washington, DC 20549.

C. Respondent shall comply with the undertakings enumerated in Section III. above.

By the Commission.

Brent J. Fields
Secretary