

Washington, D.C. 20201

September 21, 2011

**TO:** Francis S. Collins, M.D., Ph.D.

Director

National Institutes of Health

**FROM:** /Daniel R. Levinson/

Inspector General

**SUBJECT:** Appropriations Funding for National Institute of Allergy and Infectious Diseases

Contract N01-AI-3-0052 With Avecia Biologics Limited (A-03-10-03117)

The attached final report provides the results of our review of appropriations funding for National Institute of Allergy and Infectious Diseases contract N01-AI-3-0052 with Avecia Biologics Limited.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (OIG) post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at <a href="http://oig.hhs.gov">http://oig.hhs.gov</a>.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Lori S. Pilcher, Assistant Inspector General for Grants, Internal Activities, and Information Technology Audits, at (202) 619-1175 or through email at <a href="Lori.Pilcher@oig.hhs.gov">Lori.Pilcher@oig.hhs.gov</a>. We look forward to receiving your final management decision within 6 months. Please refer to report number A-03-10-03117 in all correspondence.

Attachment

# Department of Health and Human Services

# OFFICE OF INSPECTOR GENERAL

# APPROPRIATIONS FUNDING FOR NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES CONTRACT NO1-AI-3-0052 WITH AVECIA BIOLOGICS LIMITED



Daniel R. Levinson Inspector General

> September 2011 A-03-10-03117

# Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

### Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

### Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

### Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

### Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

## **Notices**

### THIS REPORT IS AVAILABLE TO THE PUBLIC

at <a href="http://oig.hhs.gov">http://oig.hhs.gov</a>

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

### OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

### **EXECUTIVE SUMMARY**

### **BACKGROUND**

The National Institute of Allergy and Infectious Diseases (NIAID) is 1 of 27 institutes and centers of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). The NIH Office of the Director sets policy and plans, manages, and coordinates NIH-wide programs and activities. The Biomedical Advanced Research and Development Authority (BARDA) is an agency in the HHS Office of the Assistant Secretary for Preparedness and Response. Like all Federal agencies, NIAID and BARDA are required to comply with appropriations statutes when acquiring supplies and services with appropriated funds.

An agency may obligate appropriations for goods and services when (1) the purpose of the obligation or expenditure is authorized, (2) the obligation occurs within the time limits for which the appropriation is available, and (3) the obligation and expenditure are within the amounts provided by Congress.

Federal statutes limit the purpose for which an agency may use appropriations to "the objects for which the appropriations were made except as otherwise provided by law" (31 U.S.C. § 1301(a)). Federal statutes also limit the time during which an appropriation is available. A fiscal year appropriation may be obligated only to meet a legitimate, or bona fide, need arising in, or in some cases arising prior to but continuing to exist in, the appropriation's period of availability (31 U.S.C. § 1502). Congress determines the amount of funding available to an agency for the purchase of goods and services by enacting appropriations. The Antideficiency Act prohibits an agency from obligating or expending those funds in advance of or in excess of an appropriation unless specifically authorized by law (31 U.S.C. § 1341(a)(1)).

The Comptroller General has held that "the question of whether to charge the appropriation current on the date the contract is made, or to charge funds current at the time the services are rendered, depends on whether the services are 'severable' or 'entire' [nonseverable]." When services are continuing and recurring, they are severable, and the agency may fund the contract with fiscal year appropriations from the year in which services are provided, unless otherwise authorized by statute. When services are for a single outcome or effort, they are nonseverable and therefore chargeable to the fiscal year in which the contract is awarded, even though its performance may extend into subsequent fiscal years.

On September 30, 2003, NIAID awarded contract N01-AI-3-0052 (the Contract), totaling \$71.3 million, to Avecia Biologics Limited in Manchester, United Kingdom. The Contract requires the contractor to develop and produce an anthrax vaccine. We determined that the Contract is a nonseverable service contract because it represents a single undertaking and provides for a single outcome (to develop an anthrax vaccine that can be produced on a large scale) at the conclusion of the contract. NIAID made two modifications to the Contract for additional work that extended the period of performance to August 31, 2013, and increased the total amount of the Contract to \$117.7 million.

In April 2008, PharmAthene, Inc., in Annapolis, Maryland, acquired the biodefense vaccines business of Avecia Biologics Limited, which included the Contract. In April 2009, NIAID transferred to BARDA management of the Contract and the remaining \$32.5 million of obligated fiscal year 2007 funds. Subsequently, BARDA changed the contract number to HHSO100-2009-00103C. BARDA reduced the period of performance so it ended on June 30, 2011, but did not reduce the amount of the Contract.

From November 2008 through February 2009, an HHS internal review group called the "Tiger Team" assessed 176 HHS contracts, including 21 NIH contracts. The Contract was 1 of the 21 NIH contracts assessed. For 17 of the 21 contracts, the Tiger Team identified instances in which contract funding was not consistent with the current HHS Acquisition Regulation or appropriations law. The Tiger Team report did not identify its concerns or quantify funding errors by contract.

### **OBJECTIVE**

Our objective was to determine whether NIAID and BARDA funded the Contract in compliance with the purpose, time, and amount requirements specified in appropriations statutes.

### **SUMMARY OF FINDINGS**

NIAID funded the Contract in compliance with the purpose requirements of appropriations statutes. However, NIAID did not comply with the time and amount requirements specified in the statutes. NIAID funded only \$40.0 million of the \$71.3 million initial Contract obligation with fiscal year 2003 appropriations. NIAID obligated a total of \$31.3 million in violation of the bona fide needs rule: \$26.0 million of fiscal year 2004 appropriated funds and \$5.3 million of fiscal year 2005 appropriated funds. Because the Contract was for nonseverable services, NIAID was required to record the full amount of the Contract using fiscal year 2003 appropriated funds. By not doing so, NIAID potentially violated the Antideficiency Act.

To remedy the bona fide needs rule violation, NIAID will need to deobligate the fiscal years 2004 and 2005 appropriations. To remedy the potential Antideficiency Act violation, NIAID would have needed to record an obligation of \$31.3 million (\$71.3 million less \$40.0 million) using fiscal year 2003 appropriations. However, because fiscal year 2003 funds are no longer available to record the obligation, NIAID may be able to fund the deficiency by using \$31.3 million of current fiscal year appropriations provided the conditions of 31 U.S.C §§ 1553 and 1554 are met. If NIAID does not have \$31.3 million of current fiscal year appropriations or the amount exceeds the lesser of 1 percent of the current appropriation or the unexpended balance of the closed appropriation, NIAID will violate the Antideficiency Act.

NIAID correctly funded the two modifications for additional work with \$8.4 million of fiscal year 2006 appropriated funds and \$38.0 million of fiscal year 2007 appropriated funds. In April 2009, NIAID transferred the remaining Contract balance totaling \$32.5 million of fiscal year 2007 funds to BARDA, and BARDA correctly obligated those funds to the Contract.

### RECOMMENDATIONS

We recommend that NIAID:

- deobligate \$26.0 million of fiscal year 2004 appropriations and return the canceled funds to the Treasury;
- deobligate \$5.3 million of fiscal year 2005 appropriations and return the canceled funds to the Treasury;
- record the remaining \$31.3 million of the \$71.3 million Contract obligation against current fiscal year appropriations;
- report an Antideficiency Act violation if sufficient current year appropriations are not available; and
- report, in accordance with 31 U.S.C. § 1554, the adjustment to the Contract using current fiscal year appropriations.

# NATIONAL INSTITUTES OF HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, NIH concurred with the findings that the Contract is nonseverable and that it should have been funded at the time the Contract was awarded. NIH said that HHS would report the violation as required by 31 U.S.C. § 1351.

We have modified our report and recommendations to identify the funding adjustments necessary by fiscal year. As noted in the modified recommendations, NIAID must record the remaining \$31.3 million obligation using current year funds.

NIH's comments are included in their entirety as the Appendix.

### TABLE OF CONTENTS

<u>Page</u>
INTRODUCTION1
BACKGROUND1
Federal Appropriations Statutes1
National Institute of Allergy and Infectious Diseases Contract Award2
Departmental Review of National Institutes of Health Contracts2
OBJECTIVE, SCOPE, AND METHODOLOGY2
Objective2
Scope3
Methodology3
FINDINGS AND RECOMMENDATIONS
FUNDING VIOLATIONS4
Bona Fide Needs Rule Violation4
Potential Antideficiency Act Violation4
CAUSES OF FUNDING VIOLATIONS
RECOMMENDATIONS5
NATIONAL INSTITUTES OF HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

### **APPENDIX**

NATIONAL INSTITUTES OF HEALTH COMMENTS

### INTRODUCTION

### **BACKGROUND**

The National Institute of Allergy and Infectious Diseases (NIAID) is 1 of 27 institutes and centers of the National Institutes of Health (NIH), an agency of the Department of Health and Human Services (HHS). The NIH Office of the Director sets policy and plans, manages, and coordinates NIH-wide programs and activities. The Biomedical Advanced Research and Development Authority (BARDA) is an agency in the HHS Office of the Assistant Secretary for Preparedness and Response. Like all Federal agencies, NIAID and BARDA are required to comply with appropriations statutes when acquiring supplies and services with appropriated funds.

### **Federal Appropriations Statutes**

An agency may obligate appropriations for goods and services when (1) the purpose of the obligation or expenditure is authorized, (2) the obligation occurs within the time limits for which the appropriation is available, and (3) the obligation and expenditure are within the amounts provided by Congress.

Federal statutes limit the purpose for which an agency may use appropriations to "the objects for which the appropriations were made except as otherwise provided by law" (31 U.S.C. § 1301(a)). A fiscal year appropriation may be obligated only to meet a legitimate, or bona fide, need arising in, or in some cases arising prior to but continuing to exist in, the appropriation's period of availability (31 U.S.C. § 1502(a)). Unless otherwise specified in the appropriation, the period of availability for most funds is the fiscal year for which the appropriation is made.

Bona fide needs may involve transactions that cover more than 1 fiscal year, depending on the nature of the services involved: "The general rule is that the fiscal year appropriation current at the time the contract is made is chargeable with payments under the contract, although performance thereunder may extend into the ensuing fiscal year" (23 Comp. Gen. 370, 371 (1943)). Multiyear contracting authority provided by statute is an exception to the bona fide needs rule.

The Comptroller General has held that "the question of whether to charge the appropriation current on the date the contract is made, or to charge funds current at the time the services are rendered, depends on whether the services are 'severable' or 'entire' [nonseverable]." When services are continuing and recurring, they are severable, and the agency may fund the contract with separate subsequent fiscal year appropriations. A contract for a single outcome or effort is chargeable to the fiscal year in which it is awarded, even though its performance may extend into subsequent fiscal years. The Comptroller General has explicitly held that incremental funding (i.e., other than full funding) of nonseverable service contracts violates the bona fide needs rule without statutory authority (71 Comp. Gen. 428 (1992)).

1

<sup>&</sup>lt;sup>1</sup> As cited in GAO-04-261SP, Appropriations Law, Vol. I, p. 5-24.

<sup>&</sup>lt;sup>2</sup> As cited in GAO-04-261SP, Appropriations Law, Vol. I, p. 5-23.

Congress determines the amount of funding available to an agency by enacting appropriations to cover programs, projects, purchases, and services needed by the agency during the period for which the funds are made available. The Antideficiency Act prohibits an agency from obligating or expending funds in advance of or in excess of an appropriation unless specifically authorized by law (31 U.S.C. § 1341(a)(1)). The Antideficiency Act requires agencies to report violations to the President and to Congress, with a copy to the Comptroller General (31 U.S.C. § 1351). The Office of Management and Budget (OMB) Circular A-11, *Preparation, Submission and Execution of the Budget*, pt. 4, § 145, prescribes the methodology for this reporting.

### **National Institute of Allergy and Infectious Diseases Contract Award**

On September 30, 2003, NIAID awarded contract N01-AI-3-0052 (the Contract), totaling \$71.3 million, to Avecia Biologics Limited in Manchester, United Kingdom. The Contract requires the contractor to develop and produce an anthrax vaccine. We determined that the Contract is a nonseverable service contract because it represents a single undertaking and provides for a single outcome (to develop an anthrax vaccine that can be produced on a large scale) at the conclusion of the contract. NIAID made two modifications to the Contract for additional work that extended the period of performance to August 31, 2013, and increased the total amount of the Contract to \$117.7 million. In fiscal year 2006, the first modification added \$8.4 million for additional work and extended the period of performance to August 31, 2009. In fiscal year 2007, the second modification added \$38.0 million for additional work and extended the period of performance to August 31, 2013.

In April 2008, PharmAthene, Inc., in Annapolis, Maryland, acquired the biodefense vaccine business of Avecia Biologics Limited, which included the Contract. In April 2009, NIAID transferred to BARDA the management of the Contract and the remaining \$32.5 million of obligated fiscal year 2007 funds. Subsequently, BARDA changed the Contract number to HHSO100-2009-00103C. BARDA reduced the period of performance so it ended on June 30, 2011, but did not reduce the amount of the Contract.

### **Departmental Review of National Institutes of Health Contracts**

In 2008, HHS management formed an internal review group of program, contract, and financial personnel called the "Tiger Team." From November 2008 through February 2009, the Tiger Team assessed 176 HHS contracts, including 21 NIH contracts. The Contract was 1 of the 21 NIH contracts assessed. For 17 of the 21 contracts, the Tiger Team identified instances in which contract funding was not consistent with the current HHS Acquisition Regulation (HHSAR) or appropriations law. The Tiger Team report did not identify its concerns or quantify funding errors by contract.

### **OBJECTIVE, SCOPE, AND METHODOLOGY**

### **Objective**

Our objective was to determine whether NIAID and BARDA funded the Contract in compliance with the purpose, time, and amount requirements specified in appropriations statutes.

<sup>&</sup>lt;sup>3</sup> Funding Multiple Year Contracts; Tiger Team Summary Report, July 29, 2009.

### Scope

We reviewed all obligations and payments made under the Contract during fiscal years 2003 through 2009. We did not review NIAID's or BARDA's internal controls because our objective did not require such a review.

We performed our fieldwork at BARDA in the District of Columbia.

### Methodology

To accomplish our objective, we:

- reviewed appropriations and acquisition laws and regulations and Contract requirements;
- reviewed the Tiger Team report;
- reviewed Contract file documentation, including the statement of work, to determine the nature of the products or services to be provided; and
- analyzed funding documents and payment invoices to determine what appropriations were obligated, recorded, and expended.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

### FINDINGS AND RECOMMENDATIONS

NIAID funded the Contract in compliance with the purpose requirements of appropriations statutes. However, NIAID did not comply with the time and amount requirements specified in the statutes. NIAID funded only \$40.0 million of the \$71.3 million initial Contract obligation with fiscal year 2003 appropriations. NIAID obligated \$31.3 million in violation of the bona fide needs rule: \$26.0 million of fiscal year 2004 appropriated funds and \$5.3 million of fiscal year 2005 appropriated funds. Because the Contract was for nonseverable services, NIAID was required to record the full amount of the Contract using fiscal year 2003 appropriated funds. By not doing so, NIAID potentially violated the Antideficiency Act.

To remedy the bona fide needs rule violation, NIAID will need to deobligate the fiscal years 2004 and 2005 appropriations. To remedy the potential Antideficiency Act violation, NIAID would have needed to record an obligation of \$31.3 million (\$71.3 million less \$40.0 million) using fiscal year 2003 appropriations. However, because fiscal year 2003 funds are no longer available to record the obligation, NIAID may be able to fund the deficiency by using \$31.3 million of current fiscal year appropriations provided the conditions of 31 U.S.C §§ 1553 and 1554 are met. If NIAID does not have \$31.3 million of current fiscal year appropriations or the amount exceeds the lesser of 1 percent of the current appropriation or the unexpended balance of the closed appropriation, NIAID will violate the Antideficiency Act.

NIAID correctly funded the two modifications for additional work with \$8.4 million of fiscal year 2006 appropriated funds and \$38.0 million of fiscal year 2007 appropriated funds. In April 2009, NIAID transferred the remaining Contract balance totaling \$32.5 million of fiscal year 2007 funds to BARDA, and BARDA correctly obligated those funds to the Contract.

### **FUNDING VIOLATIONS**

### **Bona Fide Needs Rule Violation**

Federal statutes limit the time for which an appropriation may be used. A fiscal year appropriation may be obligated only to meet a legitimate, or bona fide, need arising in, or in some cases arising prior to but continuing to exist in, the appropriation's period of availability (31 U.S.C. § 1502(a)). Bona fide needs may involve transactions that cover more than 1 fiscal year, depending on the nature of the services involved. A contract for nonseverable services must reflect a bona fide need identified in the fiscal year in which the agency awards the contract, although the contract's performance may extend into subsequent fiscal years. An agency must fully fund a nonseverable service contract by obligating funds representing the entire amount of the contract from appropriations available during the fiscal year in which the agency awards the contract.

NIAID initially awarded the 3-year<sup>4</sup> nonseverable service Contract in fiscal year 2003 and incurred an obligation totaling \$71.3 million based on an existing bona fide need. However, NIAID recorded only \$40.0 million of the obligation with fiscal year 2003 appropriations. Subsequently, NIAID improperly recorded obligations totaling \$31.3 million: \$26.0 million using fiscal year 2004 funds and \$5.3 million using fiscal year 2005 funds. However, NIAID did not have a bona fide need in fiscal years 2004 and 2005. To remedy the violation, NIAID will need to deobligate the funds improperly obligated in fiscal years 2004 and 2005.

In fiscal year 2006, NIAID extended the Contract, increased the scope of work, and correctly obligated \$8.4 million using fiscal year 2006 funds. In fiscal year 2007, NIAID again extended the Contract, increased the scope of work, and correctly obligated \$38.0 million using fiscal year 2007 funds. BARDA subsequently reduced the period of performance, but it did not reduce the amount of the Contract.

### **Potential Antideficiency Act Violation**

Congress determines the amount of funding available to an agency by enacting appropriations to cover programs, projects, purchases, and services needed by the agency during the period for which the funds are made available. The Antideficiency Act prohibits the agency from obligating or expending any amount in advance of or in excess of an appropriation unless specifically authorized by law (31 U.S.C. § 1341(a)(1)). The Antideficiency Act requires

\_

<sup>&</sup>lt;sup>4</sup> The Contract's period of performance was actually 3 years and 16 days: September 30, 2003, through October 13, 2006. Subsequently, NIAID extended the period of performance through August 31, 2013, and BARDA reduced the period of performance so it ended on June 30, 2011.

<sup>&</sup>lt;sup>5</sup> Pursuant to 31 U.S.C § 1552, appropriations from fiscal years 2004 and 2005 are closed and the funds must be returned to the Treasury.

agencies to report violations to the President and to Congress, with a copy to the Comptroller General (31 U.S.C. § 1351). OMB Circular A-11, pt. 4, § 145, prescribes the methodology for this reporting.

Pursuant to 31 U.S.C. §§ 1551-1553, the account<sup>6</sup> closing statutes, after fiscal year appropriations expire they remain available to record, adjust, and liquidate obligations properly chargeable to the appropriation account for up to 5 years. After 5 years, the appropriation account is closed and the balance is canceled.

Pursuant to 31 U.S.C. § 1553(b), if fiscal year funds are no longer available because an account has been closed, an agency may charge the obligation to the current fiscal year appropriation account available for the same purpose. The amount charged to the current fiscal year appropriation account may not exceed the lesser of 1 percent of the current appropriation or the unexpended balance of the closed appropriation.

Pursuant to 31 U.S.C. § 1554, after the close of each fiscal year, the head of each agency must submit to the President and the Secretary of the Treasury a report on adjustments made to appropriation accounts during the year, including any adjustments to obligations pursuant to section 1553.

NIAID should have recorded the full fiscal year 2003 obligation for \$71.3 million at the time of the Contract award. Instead, NIAID recorded only \$40.0 million of the obligations with fiscal year 2003 appropriations. Because fiscal year 2003 funds are no longer available to record the obligation, NIAID may be able to fund the deficiency by using \$31.3 million of current fiscal year appropriations provided the conditions of 31 U.S.C §§ 1553 and 1554 are met. If NIAID does not have \$31.3 million of current fiscal year appropriations available or the amount exceeds the lesser of 1 percent of the current appropriation or the unexpended balance of the closed appropriation, it will violate the Antideficiency Act.

### **CAUSES OF FUNDING VIOLATIONS**

Generally, the Tiger Team report attributed funding violations to:

- widespread misunderstanding of appropriations laws because of conflicting HHSAR guidance over the past 25 years;
- the use of incremental funding in ways that were not consistent with the current HHSAR and appropriations law; and
- the need for additional training and a broader understanding of appropriations law among acquisition, budget, and program staff.

-

<sup>&</sup>lt;sup>6</sup> Each agency has an account, maintained by the Department of the Treasury, that tracks the amount of funds available for use. That account is credited with funds appropriated in the agency's budget and reduced by expenditures made by the agency to perform the tasks for which the credit was given.

The Tiger Team did not identify the specific reasons for funding violations for each contract reviewed. HHS management corrected the conflicting guidance in HHSAR 332.702(a) and reissued it on December 20, 2006, more than 3 years after NIAID awarded the Contract.

### RECOMMENDATIONS

We recommend that NIAID:

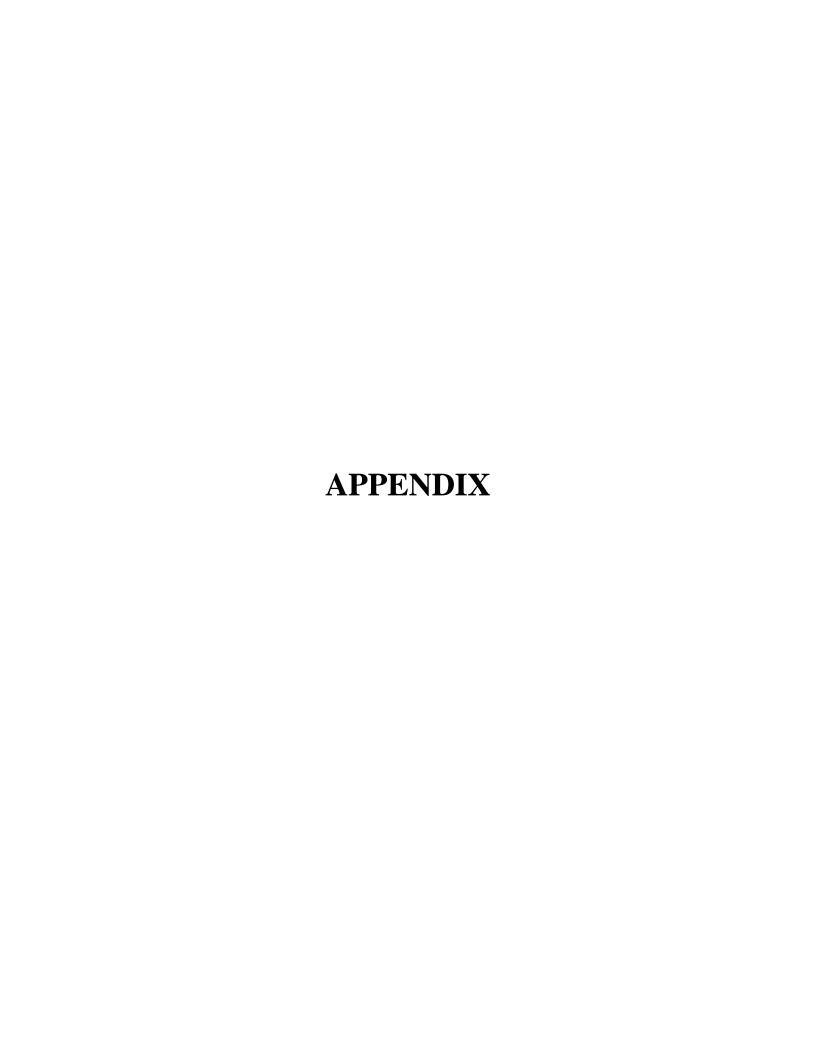
- deobligate \$26.0 million of fiscal year 2004 appropriations and return the canceled funds to the Treasury;
- deobligate \$5.3 million of fiscal year 2005 appropriations and return the canceled funds to the Treasury;
- record the remaining \$31.3 million of the \$71.3 million Contract obligation against current fiscal year appropriations;
- report an Antideficiency Act violation if sufficient current year appropriations are not available; and
- report, in accordance with 31 U.S.C. § 1554, the adjustment to the Contract using current fiscal year appropriations.

# NATIONAL INSTITUTES OF HEALTH COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, NIH concurred with the findings that the Contract is nonseverable and that it should have been funded at the time the Contract was awarded. NIH said that HHS would report the violation as required by 31 U.S.C. § 1351.

We have modified our report and recommendations to identify the funding adjustments necessary by fiscal year. As noted in the modified recommendations, NIAID must record the remaining \$31.3 million obligation using current year funds.

NIH's comments are included in their entirety as the Appendix.



### NATIONAL INSTITUTES OF HEALTH COMMENTS



### **DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

National Institutes of Health Bethesda, Maryland 20892

JUL 1 1 2011

TO:

Daniel R. Levinson

Inspector General, HHS

FROM:

Director, National Institutes of Health

SUBJECT: Response to OIG Draft Report, Appropriations Funding for National Institute of

Allergy and Infectious Diseases Contract N01-A1-3-0052 With Avecia Biologics

Limited (A-03-10-03117)

Attached are the National Institutes of Health's comments on the Office of Inspector General's draft report entitled, Appropriations Funding for National Institute of Allergy and Infectious Diseases Contract N01-AI-3-0052 With Avecia Biologics Limited (A-03-10-03117).

We appreciate the opportunity to review and comment on this important topic. We have provided general comments that address the findings and recommendations in the draft report. Should you have questions or concerns regarding our comments, please contact Meredith Stein in the Office of Management Assessment at 301-402-8482.

Francis S. Collins, M.D., Ph.D.

Travers V. Colem

Attachment

GENERAL COMMENTS ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL DRAFT REPORT ENTITLED, APPROPRIATIONS FUNDING FOR NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES CONTRACT NO1-AI-3-0052 WITH AVECIA BIOLOGICS LIMITED (A-03-10-03117)

The National Institutes of Health (NIH) appreciates the review conducted by the Office of the Inspector General (OIG) and the opportunity to provide clarification on this draft report. NIH respectfully submits the following comments:

### Summary of OIG Findings:

- The National Institute of Allergy and Infectious Diseases (NIAID) did not comply with the time requirements and may not have complied with the amount requirements specified in the appropriations statutes. NIAID funded only \$40 million of the \$71.3 million initial contract obligation with fiscal year 2003 appropriations. NIAID obligated a total of \$31.3 million in violation of the *bona fide* needs rule: \$26 million of fiscal year 2004 appropriated funds and \$5.3 million of fiscal year 2005 appropriated funds.
- Because the contract was for nonseverable services, NIAID was required to record the full amount of the contract using fiscal year 2003 appropriated funds.

### Summary of OIG Recommendations:

- NIAID should record the remaining \$31.3 million of the \$71.3 million contract obligation against fiscal year 2003 funds and deobligate funds appropriated for years other than fiscal year 2003.
- NIAID must report an Antideficiency Act violation if fiscal year 2003 funds are not available.

### NIH Comments:

The NIH concurs that NIAID Contract N01-AI-3-0052 is a nonseverable services contract and that under Federal appropriations law the contract should have been funded from the fiscal year current at the time the contract was awarded. The NIH concurs with OIG's findings as summarized above. Accordingly, NIH understands that the Department of Health and Human Services (HHS) will report the violation as required by 31 U.S.C. § 1351. NIH further understands that the HHS report will identify the proposed actions taken to correct the systemic problems within HHS which led to this and other violations.