

for patients, enhancements to the biosimilar biological review program require that FDA hire and retain sufficient numbers and types of technical and scientific experts to efficiently conduct reviews of 351(k) applications. In order to strengthen this core function and increase public access to biosimilar biological products, the FDA will commit to do the following:

A. Completion of Modernization of the Hiring System Infrastructure and Augmentation of System Capacity

1. Complete implementation of FTE-based position management system capability.

a. FDA will complete development of position management baseline accounting of all current positions and FTE counts engaged in the biosimilar biological product review program for each applicable Center and Office including filled and vacant positions, a governance structure for on-going position management that will be accountable to FDA senior management, and position management policy and guidelines ratified by FDA senior management, outlining processes for adding new positions, deleting positions, and changing established positions.

b. FDA will complete implementation of the new position-based management system.

2. Complete implementation of an online position classification system

a. FDA will finalize the establishment of an online Position Description (PD) library. The library will include all current well-classified PDs and current standardized PDs. Once operational, any new PDs classified using the on-line classification tools, and any newly created standardized PDs, will be stored and accessible within FDA's PD library and available for FDA-wide use as appropriate.

3. Complete implementation of corporate recruiting

a. For key scientific and technical disciplines commonly needed across offices engaged in the biosimilar biological product review program, FDA will complete the transition from the use of individual vacancy announcements for individual offices to expanded use of a common vacancy announcement and certificate of eligible job applicants that can be used by multiple offices. As a part of this effort, FDA will complete the transition from use of individual announcements that are posted for a limited period to common vacancy announcements with open continuous posting to maximize the opportunity for qualified applicants to apply for these positions.

B. Augmentation of Hiring Staff Capacity and Capability

In recognition of the chronic and continuing difficulties of recruiting and retaining sufficient numbers of qualified Human Resources (HR) staff, FDA will engage a qualified contractor to provide continuous support throughout BsUFA II to augment the existing FDA HR staff capacity and capabilities. The utilization of a qualified contractor will assist FDA in successfully accomplishing BsUFA II goals for recruitment and retention of biosimilar biological product review program staff.

C. Complete Establishment of a Dedicated Function to Ensure Needed Scientific Staffing for Human Drug Review Including for Review of Biosimilar Biological Products

1. Rapid advances in the science and technology of biosimilar biological product development and manufacturing require FDA's biosimilar biological product review program staff to keep pace with science and learn innovative methods and techniques for review of new therapies. FDA will complete the establishment of a new dedicated unit within the Office of Medical Products and Tobacco

charged with the continuous recruiting, staffing, and retention of scientific, technical, and professional staff for the PDUFA and BsUFA review programs.

a. The unit will continuously develop and implement scientific staff hiring strategies and plans, working closely with the center review offices and the FDA HR office, to meet discipline-specific hiring commitments and other targeted staffing needs. It will function as a scientific-focused recruiter conducting ongoing proactive outreach to source qualified candidates, and conducting competitive recruiting to fill vacancies that require top scientific, technical, and professional talent.

b. The unit will conduct analyses, no less than annually, of compensation and other factors affecting retention of key staff in targeted disciplines and provide leadership and support for agency compensation oversight boards that currently exist or may be established as needed to ensure retention of key scientific, technical, and professional staff.

D. Set Clear Goals for Biosimilar Biological Product Review Program Hiring

1. FDA will establish priorities for management of the metric goals for targeted hires within the biosimilar biological product review program staff for BsUFA II. In particular, FDA will target hiring 15 FTE in FY 2018, to enhance capacity for biosimilar guidance development, reviewer training, and timely communication.

2. FDA will confirm progress in the hiring of BsUFA I FTEs. FDA will report on progress against the hiring goal for BsUFA II on a quarterly basis posting updates to the FDA website BsUFA Performance webpage.

E. Comprehensive and Continuous Assessment of Hiring and Retention

FDA hiring and retention of staff for the biosimilar biological product review program will be evaluated by a qualified, independent contractor with expertise in assessing HR operations and transformation. The BsUFA II assessment will be conducted under the same contract and by the same independent contractor that will conduct the assessment related to hiring and retention of staff for the human drug review program in PDUFA VI. It will include continuous assessments throughout the course of implementation of the performance initiatives identified in Sections V.A-D, and metrics including, but not limited to, those related to recruiting and retention in the PDUFA and BsUFA review programs including, but not limited to, specifically targeted scientific disciplines and levels of experience. The contractor will conduct a comprehensive review of current hiring processes and hiring staff capacity and capabilities that contribute to achievement of successes, potential problems, or delays in PDUFA or BsUFA review program staff hiring. This includes the entire hiring function and related capabilities. FDA and regulated industry leadership will periodically and regularly assess the progress of hiring and retention throughout BsUFA II.

1. Initial Assessment: The assessment will include an initial baseline assessment to be conducted and completed no later than December 31, 2017. The initial baseline study will include an evaluation of the current state and provide recommended options to address any identified gaps or areas identified as priorities for improvement, and a study report to be published no later than December 31, 2017. FDA will hold a public meeting no later than December 31, 2017, to present and discuss report findings, and present its specific plans, including agency senior management oversight, and timeline for implementing recommended enhancements to be fully operational by no later than December 31, 2018.

2. Interim Assessment: An interim assessment will be published by March 31, 2020, for public comment. By June 30, 2020, FDA will hold a public meeting during which the public may present their views. FDA will discuss the findings of the interim assessment, including progress relative to program milestones and metrics, and other aggregated feedback from internal customers and participants in HR services that may be included in the continuous assessment. FDA will also address any issues identified to date including actions proposed to improve the likelihood of success of the program.

3. Final Assessment: A final assessment will be published by December 31, 2021, for public comment. FDA will hold a public meeting by no later than March 30, 2022, during which the public may present their views. FDA will discuss the findings of the final assessment, including progress relative to program milestones and metrics, and other aggregated feedback from internal customers and participants in HR services that may be included in the continuous assessment. FDA will also address any issues identified and plans for addressing these issues.

V. DEFINITIONS AND EXPLANATION OF TERMS

A. The term "review and act on" means the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

B. A resubmitted original application is a complete response to an action letter addressing all identified deficiencies.

ARMS SALES NOTIFICATION

Mr. CORKER. Mr. President, section 36(b) of the Arms Export Control Act requires that Congress receive prior notification of certain proposed arms sales as defined by that statute. Upon such notification, the Congress has 30 calendar days during which the sale may be reviewed. The provision stipulates that, in the Senate, the notification of proposed sales shall be sent to the chairman of the Senate Foreign Relations Committee.

In keeping with the committee's intention to see that relevant information is available to the full Senate, I ask unanimous consent to have in the RECORD the notifications which have been received. If the cover letter references a classified annex, then such annex is available to all Senators in the office of the Foreign Relations Committee, room SD-423.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

DEFENSE SECURITY
COOPERATION AGENCY,
Arlington, VA.

Hon. BOB CORKER,
Chairman, Committee on Foreign Relations,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 17-38, concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Australia for defense articles and

services estimated to cost \$108.7 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

GREGORY M. KAUSNER,
Acting Director.

Enclosures.

TRANSMITTAL NO. 17-38

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) Prospective Purchaser: Government of Australia.

(ii) Total Estimated Value:

Major Defense Equipment \$0.0 million

Other \$108.7 million

Total \$108.7 million

(iii) Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:

Major Defense Equipment (MDE): None

Non-MDE includes:

One thousand nine hundred fifty-two (1,952) ALE-70(V)/T-1687A Electronic Towed Decoy Countermeasures, publications and technical documentation, other technical assistance, U.S. Government and contractor engineering, technical and logistics support services, and other related elements of logistical and program support.

(iv) Military Department: Navy (XX-P-AMN A1)

(v) Prior Related Cases, if any: None

(vi) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None

(vii) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Attached Annex

(viii) Date Report Delivered to Congress: August 02, 2017.

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Australia—ALE-70 Radio Frequency Countermeasures (RFCM)

The Government of Australia has requested the possible sale of one thousand nine hundred fifty-two (1,952) ALE-70(V)/T-1687A Electronic Towed Decoy Countermeasures, publications and technical documentation, other technical assistance, U.S. Government and contractor engineering, technical and logistics support services, and other related elements of logistical and program support. The total estimated program cost is \$108.7 million.

This sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a major non-NATO ally and continues to be an important force for political stability, security, and economic development in the Western Pacific. It is vital to the U.S. national interest to assist our ally in developing and maintaining a strong and ready self-defense capability.

The proposed sale will improve Australia's F-35 survivability and will enhance its capability to deter global threats, strengthen its homeland defense, and cooperate in coalition defense initiatives. Australia will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be British Aerospace Enterprise (BAE), Nashua, NH. There are no offsets proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Australia.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

TRANSMITTAL NO. 17-38

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex Item No. vii

(vii) Sensitivity of Technology:

1. The ALE-70 is a towed radio frequency countermeasure designed for deployment from the F-35 aircraft and is comprised of electronic and mechanical sub-assemblies to accomplish the intended purpose. The ALE-70 consists of three major components: the reel/launcher assembly, the tow line, and the T-1687 countermeasure transmitter. Upon deployment from the aircraft, the countermeasure transmitter is reeled out to a prescribed distance, held in tow behind the jet by the tow line and emits waveforms in response to commands from the countermeasure controller located in the jet. The waveforms are utilized to confuse or decoy adversary radars or radar guided weapons. Designed and produced by BAE Systems of Nashua, New Hampshire, the ALE-70 employs amplifiers based on Gallium Nitride (GaN) technology to meet stringent output requirements.

2. The ALE-70 generates, amplifies, and transmits signals in response to commands from the countermeasures controller which remains aboard the jet. Neither the countermeasure transmitter nor the reel/launcher assembly contains stored information or software representing critical program information. As the ALE-70 contains no software or stored waveforms/techniques, Anti-Tampering security measures are not required. ALE-70 hardware is classified SECRET to protect specific data elements associated with the performance of the countermeasure.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent system which might reduce system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that Australia can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to Australia.

DEFENSE SECURITY
COOPERATION AGENCY,
Arlington, VA.

Hon. BOB CORKER,
Chairman, Committee on Foreign Relations U.S.
Senate, Washington, DC.

DEAR MR. CHAIRMAN: Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 16-55, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to the Federal Republic of Nigeria for defense articles and services estimated to cost \$593 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

GREGORY M. KAUSNER,
Acting Director.

Enclosures.

TRANSMITTAL NO. 16-55

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) Prospective Purchaser: The Federal Republic of Nigeria

(ii) Total Estimated Value:

Major Defense Equipment \$29 million

Other \$564 million

Total \$593 million

(iii) Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:

Major Defense Equipment (MDE):

One hundred (100) GBU-12 (500lb) Paveway

II (PW-II) Tailkits

One hundred (100) GBU-58 (250lb) PW-II

Tailkits

Four hundred (400) Laser Guided Rockets including Advanced Precision Kill Weapon System (APKWS)

Two thousand (2,000) MK-81 (250lb) bombs

Five thousand (5,000) 2.75 inch Hydra 70

Unguided Rockets (70mm rockets)

One thousand (1,000) 2.75 inch Hydra 70

Unguided Rockets (practice)

Twenty thousand (20,000) Rounds, .50 Caliber Machine Gun Ammo

Non-Major Defense Equipment (MDE): This request also includes the following Non-MDE: Twelve (12) A-29 Super Tucano aircraft, seven (7) AN/AAQ-22F Electro-Optical/Infrared (EO/IR) Sensor and Laser Designators, Initial Spares, Readiness Spares Package, Consumables, Support Equipment, Technical Data, Repair and Return Support, Facilities infrastructure and hangar construction, Night Vision Devices (NVDs), Contract Logistics Services (CLS), Contractor Provided Familiarization and Training, USG Manpower and Services, Field Service Representatives, Training Services (pilot training, USAF training, early A-29 training, flight leader upgrade training, travel and living allowance, maintenance training, specialized training, computer-based training, night vision device training, human rights and international humanitarian law, and munitions training), Training Simulators, Air Worthiness Support, Forward Operating Base Facilities, Forward Operating Location Support, Ferrying, and Non-recurring Engineering. Additionally, all aircraft will include weapons software to support forward looking infrared sensors (FLIRs), ancillary systems.

(iv) Military Department: Air Force (X8-D-SAB)

(v) Prior Related Cases, if any: None

(vi) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None

(vii) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Annex attached.

(viii) Date Report Delivered to Congress: Aug 02 2017

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Nigeria—A-29 Super Tucano Aircraft, Weapons and Associated Support

The Government of Nigeria requests twelve (12) A-29 Super Tucano aircraft and weapons, including all associated training, spare parts, aviation and ground support equipment, and hangar, facilities, and infrastructure required to support the program. The estimated total case value is \$593 million.

These aircraft will support Nigerian military operations against terrorist organization Boko Haram and to counter illicit trafficking in Nigeria and the Gulf of Guinea. The Super Tucano is a sustainable platform for counterterrorism, counter insurgency, border surveillance, and illicit trade interdiction operations. The proposed sale will support U.S. foreign policy objectives by helping Nigeria to meet shared counterterrorism objectives for the region. This proposed sale will strengthen the U.S. security relationship with Africa's largest democracy. Nigeria will have no difficulty absorbing these aircraft into its armed forces.

The proposed sale of this equipment and support does not alter the basic military balance in the region.

The prime contractor is the Sierra Nevada Corporation, headquartered in Centennial, Colorado. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require the assignment of U.S. Government or contractor representatives to Nigeria for mobile training teams and contract logistic support.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

TRANSMITTAL NO. 16-55

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex Item No. vii

(vii) Sensitivity of Technology:

1. This sale involves the release of sensitive weapons software technology information to Nigeria. Software associated with the following weapons will be included in the aircraft operational flight program to support a future weapons capability.

2. Sensitive and/or classified (up to SECRET) elements of the proposed A-29 sale to Nigeria includes the hardware and associated software with: Advanced Precision Kill Weapon System (APKWS) laser guided rockets, Guided Bomb Unit (GBU)-12/58 Paveway II laser guided tail kits, and Mark (MK)-81/82 general purpose bombs.

3. The Hydra 70 Rocket System is a modernized version of the 2.75 inch (70 mm) unguided rocket body with the MK66 Rocket Motor.

4. The APKWS is a low cost semi-active laser guidance kit developed by BAE Systems which is added to current unguided 70 mm rocket motors and warheads similar to and including the Hydra 70 rocket. It is a low collateral damage weapon that can effectively strike both soft and lightly armored targets. APKWS turns a standard unguided 2.75 inch (70 mm) rocket into a precision laser-guided rocket, classification up to SECRET.

5. GBU-12/58 Paveway II (PW-II) Tailkits: 500-lb (GBU-12) and 250-lb (GBU-58) are laser-guided ballistic bombs (LGBs) developed by Raytheon and Lockheed Martin. The LGB is a maneuverable, free-fall weapon that guides to a spot of laser energy reflected off of the target. The LGB is delivered like a normal general purpose (GP) warhead and the semi-active guidance corrects for many of the normal errors inherent in any delivery system. Laser designation for the weapon can be provided by a variety of laser target markers or designators. The tailkit consists of a laser guidance kit, a computer control group (CCG) and a warhead specific Air Foil Group (AFG), that attach to the nose and tail of MK 81 and MK 82 General Purpose (GP) bomb bodies to create an LGB. This sale includes the tailkits to transform Nigeria's existing 500-lb and 250-lb GP bomb bodies into GBU-12s and GBU-58s respectively. Nigeria is also buying additional GBU-58s, 250-lb (MK-81) guided bombs. The overall weapon is CONFIDENTIAL.

6. AN/AAQ-22F Brite Star Electro-Optical Infrared (EO/IR) Multi-Sensor Targeting System developed by FLIR. The system is a five field-of-view (FOV) large format thermal imager, three FOV color daylight camera with laser designator for terminal guidance of LGBs and IR-guided rockets. The system is classified as UNCLASSIFIED.

7. This sale is necessary in furtherance of U.S. foreign policy and national security objectives outlined in the Policy Justification. Moreover, the benefits to be derived from

this sale, as outlined in the Policy Justification, outweigh the potential damage that could result if the sensitive technology were revealed to unauthorized persons.

8. All defense articles and services listed in this transmittal are authorized for release and export to the Government of Nigeria.

CONFIRMATION OF CHRISTOPHER WRAY

Mr. VAN HOLLEN. Mr. President, I wish to voice my support for Christopher Wray's confirmation to be the next Director of the FBI. After meeting with Mr. Wray and reviewing his record, I believe he possesses the independence and integrity necessary to lead the Bureau through this tumultuous period.

This vacancy arose because President Trump abruptly fired then-Director James Comey. The circumstances surrounding Mr. Comey's firing are alarming and suspicious. Mr. Comey testified under oath that the President not only demanded his personal loyalty on numerous occasions but also intimated that Mr. Comey should stop investigating then-National Security Advisor Michael Flynn and Russian interference in the 2016 elections.

Mr. Wray will face numerous challenges as the new Director of the FBI. He will have to deal with a President who has shown a complete disregard for traditional protocols designed to ensure the agency's independence. During our meeting, Mr. Wray assured me that he would remain independent from the President and would reject any attempts by President Trump to inappropriately intervene in the work of the FBI.

During our meeting, I also impressed upon Mr. Wray the importance of consolidating the FBI's staff in one building. The FBI has long outgrown its current space and the building is deteriorating, which compromises the agency's mission. I look forward to working with him to give FBI personnel the facilities they deserve.

As Mr. Wray takes his position, he will need to work immediately to affirm the FBI's independence and restore the confidence of an agency shaken by the President's inappropriate conduct with respect to Mr. Comey and other matters. This Congress must conduct vigorous oversight to ensure that Mr. Wray maintains the high standard of integrity that he has promised and to respond to any attempts by the President or his political advisors to exert undue influence at the FBI. I pledge to do everything I can to support his important mission and the vital work of the FBI.

U.S.-CUBA TRADE ACT OF 2017

Mr. WYDEN. Mr. President, today I wish to propose a new day in U.S. relations with the country of Cuba. With his recent imposition of new restrictions, the President presented one vision of that relationship—one that

looks backwards and reverts to a failed policy of isolation that has done nothing to improve the lives of the Cuban people and has harmed the American economy. I would like to present an alternative vision—one that looks to the future and at fostering the exchange of ideas and commerce between the two countries.

It is often noted that Cuba is less than 100 miles away, but decades behind the United States, in no small part because of the U.S. embargo. Decades of the same, tired, failing economic policies left the Cuban Government in place and only hurt the Cuban people and American farmers and manufacturers.

As Cuban-American relations thawed under Presidents Bush and Obama, the Cuban Government decided to try something different. Private entrepreneurs are operating an increasing number of restaurants, taxis, and other tourist-related businesses. Cubans are opening up their homes for visitors to stay in and selling products directly to visiting Americans. In addition, the government's grip on information and communication is necessarily weakening as technology and the Internet inevitably permeate the country.

The U.S. has come a long way since the 1990s and hardly resembles the world of the 1960s. Our policies toward Cuba should reflect that change. The U.S.-Cuba Trade Act of 2017 would completely remove the architecture of sanctions against Cuba and establish normal trade relations with that country.

I want to be clear that this is not a free pass for the Cuban Government. I continue to have grave concerns about its suppression of pro-democracy movements, but I reject the view that continuing to try and ostracize Cuba will bring positive change. The past five decades provide empirical evidence that it will not. I also reject the cynical argument that the U.S. must choose between engagement with Cuba and support for basic human rights and dignity. Indeed, if the past half century has shown us anything, it is that smart, principled engagement is the way to bring about greater economic and political freedom for the Cuban people.

Just as important as what the embargo means for the Cuban people is what it means for U.S. farmers and businesses. Even with the changes made by the Obama administration, it remains almost impossible to do business in Cuba. Cuba is a natural customer of the United States, but restrictions on credit and travel, among others, have severely hampered the ability of U.S. exporters to do business in the Cuban market. The question is: What are we getting by surrendering a market that should be ours to the EU, China, Brazil, and others? I am afraid that the answer is nothing.

That is why I introduced the U.S.-Cuba Trade Act of 2017, to finally put an end to the ineffective embargo against Cuba.