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OFFICE OF SMALL AND DISADVANTAGED BUSINESS UTILIZATION

Doing Business with the FDA

Natasha Boyce

**Office of Small & Disadvantaged Business Utilization
U.S. Department of Health and Human Services**



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SMALL BUSINESSES ARE THE  OF THE ECONOMY





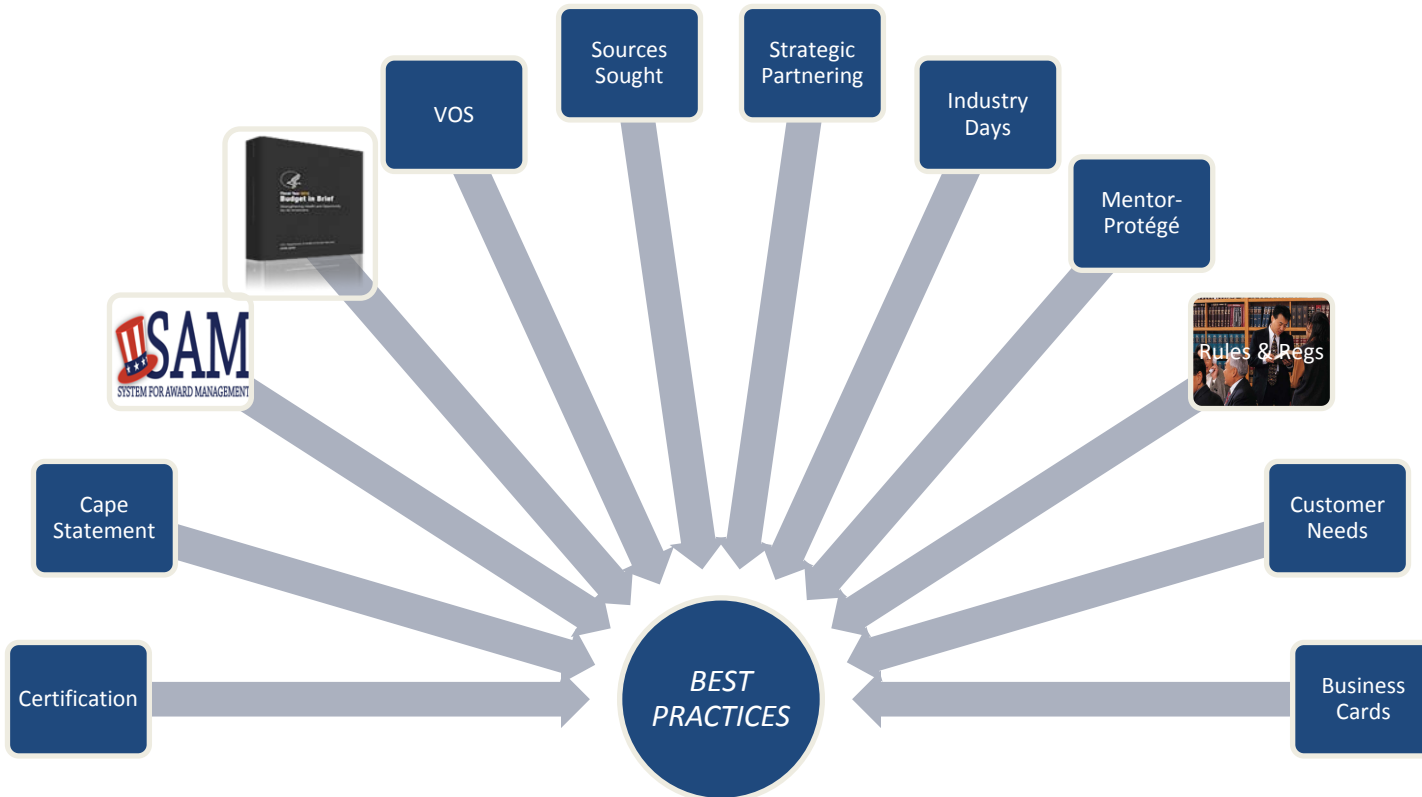
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BEST PRACTICES





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TOP TEN BEST PRACTICES





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KNOW THE ORGANIZATION'S POINTS OF CONTACT



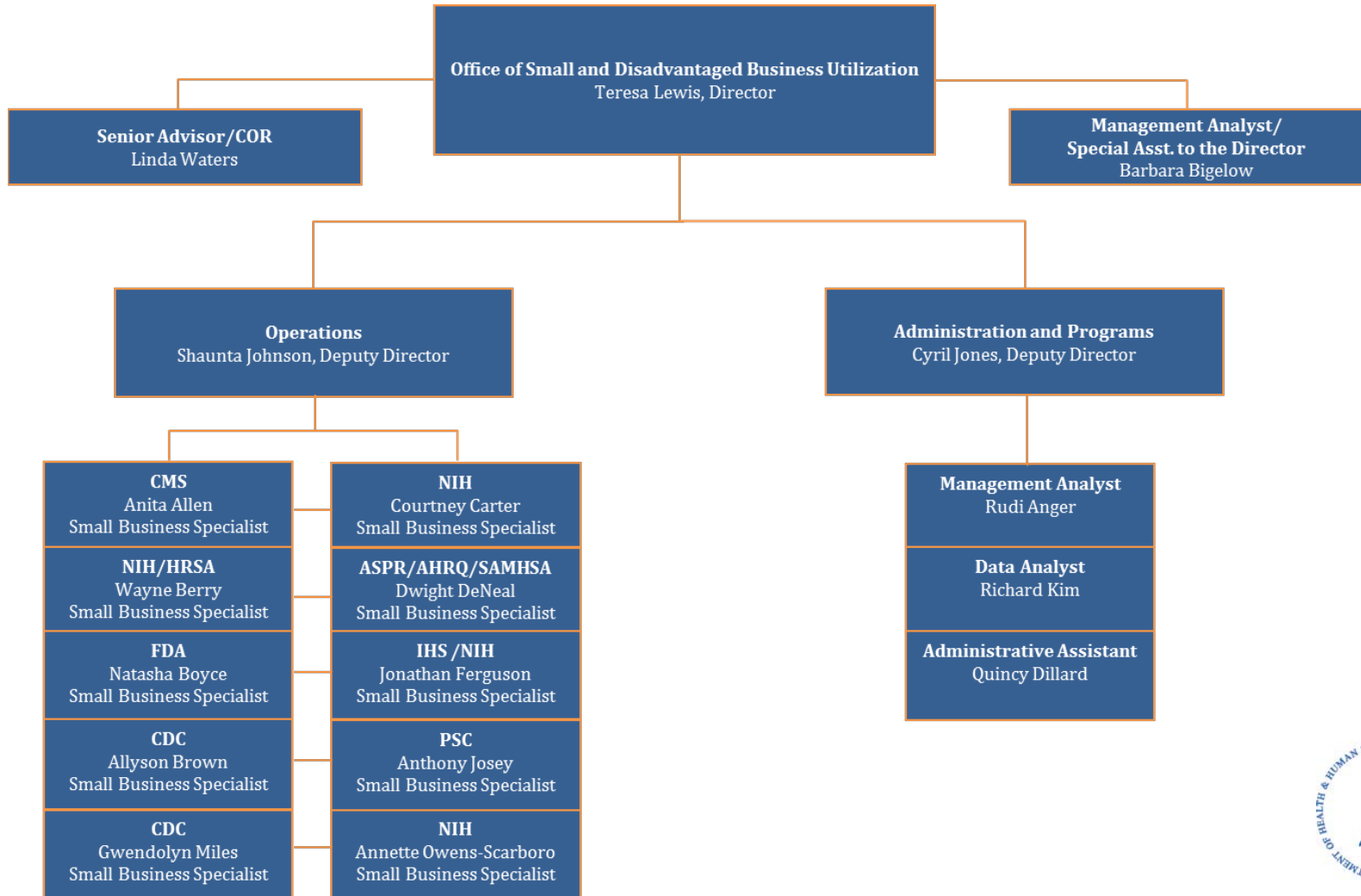


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KNOW THE ORGANIZATION'S MISSION, GOALS, TOP NAICS





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FDA's Mission

FDA is responsible for:

Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective

Protecting the public from electronic product radiation

Assuring cosmetics and dietary supplements are safe and properly labeled

Regulating tobacco products

Advancing the public health by helping to speed product innovations

Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health

* FDA's responsibilities extend to the 50 United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions.





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Small Business Socio-Economic Categories	FDA FY 15 GOAL	FDA FY 15 ACHIEVED	Total \$ Needed to Meet Goals	% Needed to Reach Goal
Small Business	41%	50.07%	Successful	
Small and Disadvantaged Business (SDB)	5%	25.65%	Successful	
Women-Owned Small Business (WOSB)	5%	13.63%	Successful	
Historically Under-Utilized Business Zone (HUBZone)	3%	2.21%	.09%	\$9,023,867
Service-Disabled Veteran-Owned Small Business (SDVOSB)	3%	3.08%	Successful ₉	



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TOP NAICS CODES

- **236220** COMMERCIAL AND INSTITUTIONAL BUILDING CONSTRUCTION
- **334516** ANALYTICAL LABORATORY INSTRUMENT MANUFACTURING
- **339113** SURGICAL APPLIANCE AND SUPPLIES MANUFACTURING
- **423430** COMPUTER AND COMPUTER PERIPHERAL EQUIPMENT AND SOFTWARE MERCHANT WHOLESALERS
- **443120** COMPUTER AND SOFTWARE STORES
- **511210** SOFTWARE PUBLISHERS
- **541511** CUSTOM COMPUTER PROGRAMMING SERVICES
- **541512** COMPUTER SYSTEMS DESIGN SERVICES
- **541513** COMPUTER FACILITIES MANAGEMENT SERVICES
- **541611** ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING SERVICES
- **541710** AND DEVELOPMENT IN THE PHYSICAL, ENGINEERING, AND LIFE SCIENCES
- **561210** FACILITIES SUPPORT SERVICES
- **561320** TEMPORARY HELP SERVICES
- **811212** COMPUTER AND OFFICE MACHINE REPAIR AND MAINTENANCE
- **923120** ADMINISTRATION OF PUBLIC HEALTH PROGRAMS





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RESEARCH RESEARCH RESEARCH





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Budget in Brief

Food and Drug Administration

The FY 2017 Budget includes \$5.1 billion in total resources for the Food and Drug Administration (FDA), an increase of \$358 million, or 8 percent above FY 2016. Of this increase, \$15 million is in budget authority, \$269 million in user fees, and \$75 million in new mandatory funding. FDA's jurisdiction of products and activities is vast, ranging from over-the-counter drugs to infant formula, and the challenges to secure the safety of these products increases in complexity with a growing global market.





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PROCUREMENT FORECAST

<http://procurementforecast.hhs.gov>

Search by:

- Operating Division
- NAICS
- Keyword





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Federal Procurement Data System - Next Generation

[» Home](#) | [» Newsroom](#) | [» Reports](#) | [» Status](#) | [» Worksite](#) | [» Archives](#) | [» Training](#) | [» Help](#) |



Login

Log-In:

Password:

- [» Forgot Your Password?](#)
- [» Security and Privacy](#)
- [» Contact Help Desk](#)

Registration

- [» Register](#)
- [» Who Should Register?](#)

FAQs

- [» FPDS-NG](#)

ezSearch

Google-like search to help you find federal contracts...

ezSearch contains procurement data as well as additional NASA data (for example, financial assistance actions).

Operation Enduring Freedom (OEF)

A new National Interest Action value 'Operation Enduring Freedom (OEF)' has been added to track the OEF contracts.

For Web Portal users the value 'Operation Enduring Freedom (OEF)' is available for selection in the National Interest Action field dropdown. The Contract Writing systems shall use the code 'O12F' when creating/updating documents through Business Services.

National Interest Action value 'Operation Enduring Freedom (OEF)' is valid from 10/01/2011 to 09/30/2014.

Enhanced Standard Reports

NIA Expiration Date Extended

1. National Interest Action value 'Gulf Oil Spill 0410' expiration date has been extended from 02/24/2012 to 08/23/2013 on FPDS-NG Production system. National Interest Action value 'Gulf Oil Spill 0410' is valid from 04/25/2010 to 08/23/2013.
2. National Interest Action value 'Hurricane Irene 2011' expiration date has been extended from 02/21/2012 to 10/22/2012 on FPDS-NG Production system. National Interest Action value 'Hurricane Irene 2011' is valid from 08/22/2011 to 10/22/2012.

Top Requests

- [» Recovery Report](#)
- [» Hurricane Irene Report](#)
- [» Pacific Earthquake/Tsunami](#)
- [» Hurricane Earl Report](#)
- [» Gulf Oil Spill Report](#)
- [» Haiti Earthquake Report](#)
- [» Hurricane Katrina Report](#)
- [» Hurricane Rita Report](#)
- [» Other Hurricane/Disaster Relief](#)

Latest News

- [» Upcoming Releases](#)
- [» Top 100 Contractors Report](#)
- [» Multiple or Single Award IDV Correction Requests](#)
- [» Software Releases](#)
- [» Data Archives](#)
- [» Operation Enduring Freedom \(OEF\)](#)





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STRATEGIC SOURCING

The Program Support Center (PSC) SSD competed and established HHS-wide Blanket Purchase Agreements (BPA) for the following commodities:

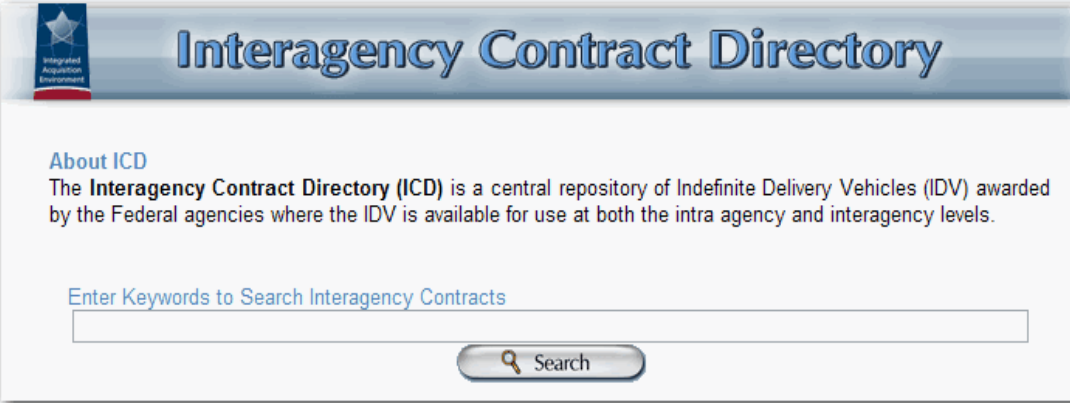
- Custodial Products
- Events Management Services
- Office Equipment
- Office Furniture
- Office Supplies
- Temporary Administrative and Professional Staffing Services
- Temporary Professional and Medical Staffing Services
- Domestic Mail
- Information Technology Peripherals and Hardware
- Laboratory Supplies





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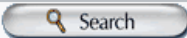
- What firms have been awarded IDIQ contracts?
- Which Blanket Purchase Agreements (BPA) are being most utilized within an agency?
- Should I position my firm to compete for GWAC contracts?



Interagency Contract Directory

About ICD
The **Interagency Contract Directory (ICD)** is a central repository of Indefinite Delivery Vehicles (IDV) awarded by the Federal agencies where the IDV is available for use at both the intra agency and interagency levels.

Enter Keywords to Search Interagency Contracts

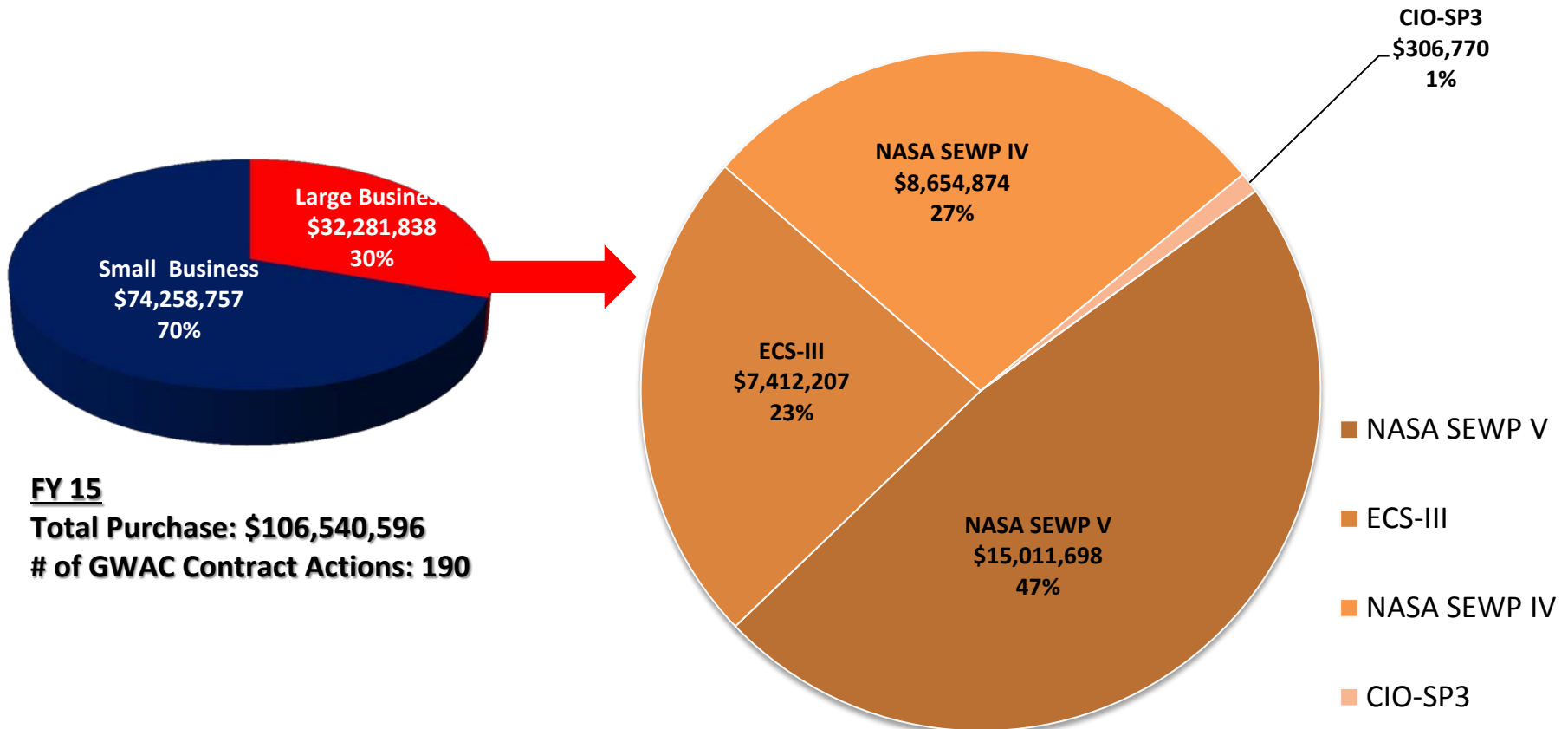
 Search

<https://www.contractdirectory.gov/contractdirectory/>



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FY 15 GWACs Utilization





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KEY GRANTS SYSTEMS

Pre-Award

- Catalog for Federal Domestic Assistance (<https://www.cfda.gov/>)
- Other Agency “Forecasting Tools” such as:
 - HHS Grants Forecast (<http://www.acf.hhs.gov/hhsgrantsforecast/>)
- System for Award Management/Central Contracting Registry (<https://www.sam.gov/sam/>)
- Grants.gov (<http://www.grants.gov/>)

Post-Award

- USASpending.gov (<http://www.usaspending.gov/>)
- Other Agency “Transparency” systems such as:
 - Tracking Accountability in Government Grants System (TAGGS) (<http://taggs.hhs.gov/>)

**ALL ALLOW PROSPECTIVE GRANTEES AND INTERESTED MEMBERS OF THE PUBLIC TO SEARCH BY
KEY WORD**





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MARKETING TOOLS





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EFFECTIVE CAPABILITY STATEMENT

- One Page/PDF
- Tailored for Audience
- NAICS
- Core Competencies
- Past Performance
- Value Proposition
- Bullet Points
- Spell Check
- Remove Jargon
- Visually Interesting

ABC SHIPPING Capability Statement
www.ABCShipping.com

Import / Export Specialists Serving the World Through International Trading and Exchange

MISSION STATEMENT
To assist the government in improving the lives of the tens of millions of people living in vulnerable countries that are suffering from disaster and plight conditions.

ABOUT US
ABC Shipping is an Import/Export market place for agricultural products and equipment, computers and electronics, machinery, cars, building materials, and healthcare products. We influence global trade by helping importers and exporters develop buyer-seller relationships.

CORE COMPETENCIES
Import and Export of the following goods by ground, air and sea which are bought & sold directly from the manufacturers:

Computers / Technology	Agricultural Products
<ul style="list-style-type: none"> > Peripherals ☐ Input / Output ☐ Storage > Hardware ☐ Software ☐ Components 	<ul style="list-style-type: none"> > Food ☐ Cocoa ☐ Rice ☐ Sugar
Healthcare Products	Construction
<ul style="list-style-type: none"> > Medical Supplies ☐ Surgical Tools ☐ Diagnostic Equipment ☐ Exam Tables 	<ul style="list-style-type: none"> > Building Materials ☐ Cement ☐ Modular Buildings
	Heavy Equipment
	<ul style="list-style-type: none"> > Cranes > Caterpillars > Road Building Equipment

DIFFERENTIATORS

Customer Oriented - ABC Shipping prides itself on its customer relations and goes above and beyond to satisfy its clients.
Research - ABC Shipping does extensive research for its clients to find the best quality product.
Value - Because of the research involved along the way, ABC Shipping offers its clients the best value for what is being sought.

COMPANY INFO
CAGE : 55555
DUNS : 555555555
Primary POC: Bob Smith
E-mail: BSmith@abcship.com
Phone: 1(555)555-5555

West Coast Office :
5555 555TH Ave NE
Kirkland, WA 98034
East Coast Office:
555 3rd Ave, 6th Floor
New York, NY 10022

Socio-Economic Factors
Small Business
SBA Cert. Small Disadvantaged
Minority Owned

NAICS
423430 Computer & Peripheral Equipment Wholesalers
423450 Medical, Dental, and Hospital Supplies Wholesalers
423610 Electrical Apparatus and Equipment Wholesalers
423820 Farm and Garden Machinery Wholesalers
488510 Freight Transportation Arrangement





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BUSINESS CARDS (front)



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nar@aceinfosolutions.com

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- 70, B(a) STARS, MOBIS
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www.aceinfosolutions.com

QA Stds



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Enterprise Architecture ~ SOA ~ Data Management

Pool Roy, BEng, MBA
President

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Cell: (301) 252-7292
Fax: (301) 977-6016

GSA 8(a), 508, MBE
GS-35F-6648M

**NAICS: 541511, 541512,
541513, 541519, 541690**

GSA Sched#

NAICS



Service Disabled Veteran Owned Small Business
Management Support Technology, Inc.

Government Financial Management, Information
Management, and Program Management

Professional
Services

Thomas W. Hodge
Director of Business Development

9990 Fairfax Boulevard, Suite # 300
Fairfax, VA 22030-1720
Tel: (703) 385-5841 x 212
Fax: (703) 385-5843
Cell: (703) 343-3481
Email: thodge@msti-net.com Website: www.msti-net.com

GSA ★
HUB 9001:2000
Certified

Cape Keywords



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BUSINESS CARDS (back)

Contracting Vehicles

- GSA IT Schedule 70
- State of Maryland (CATS)

Classifications

- SBA 8(a)
- SBA SDB

State Contract

Primary NAICS Codes

334611	518112	518210	541511
541512	541513	541519	541611
541612	541618	541710	561410
561439	611420	611519	811212

CAGE/NCAGE Code: 01JL9

GSA Schedules & SIN

"Delivering best value that makes the difference"

GSA FABs: GS-23F-0310N
 . Special Item No. 520-3 Due Diligence and Support Services
 . Special Item No. 520-11 Accounting Services

Primary NAICS Codes
 518210, 522390, 531390, 541211, 541219, 541611, 541618, 561990

Women-Owned Business

GSA: GS-25F-0065N
 LSDBE Certified LS 06200414794
 DC Supply Schedule DS-C-1-600-38-C-002
 8(a) pending
 INC ICCI 100 Alumni 2000

State Contract

NAICS CODES:

323115	811212	561439
453210	323110	323114
541430	323111	561210

Cape Keywords

CAPABILITIES

- Systems Integration
- Enterprise Architecture
- Enterprise Resource Planning (ERP)
- Customer Relations Mgmt. (CRM)
- Data Warehousing, ETL Process
- Business Intelligence(BI)
- Web/Portal Development
- Database Management
- Custom Application Development
- Project Management

NAICS CODES

- 518210 - Data Processing, Hosting, and Related Services
- 519130 - Internet Publishing and Web Search Portals
- 519190 - All Other Information Services
- 541511 - Custom Computer Programming Services
- 541512 - Computer Systems Design Services
- 541513 - Computer Facilities Management Services
- 541519 - Other Computer Related Services
- 541611 - Admin. Mgmt. & General Mgmt. Consulting Services
- 541612 - Human Resources & Exec. Search Consulting Svcs.
- 541618 - Other Management Consulting Services
- 541990 - All Other Professional, Scientific, & Technical Svcs.

SBA certified 8(a) SDB * Woman Owned Small Business
 SWAM - Virginia Dept. Of Minority Business Enterprise
 State of MD DoIT CATS-II Contract
 CAGE: 1T6A4 **DUNS#** 010228836

State Certs



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RESPOND TO SOURCES SOUGHT NOTICES





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NETWORK



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TRADE ASSOCIATIONS
VENDOR OUTREACH SESSIONS
INDUSTRY DAYS
MENTOR-PROTEGE
JOINT VENTURES





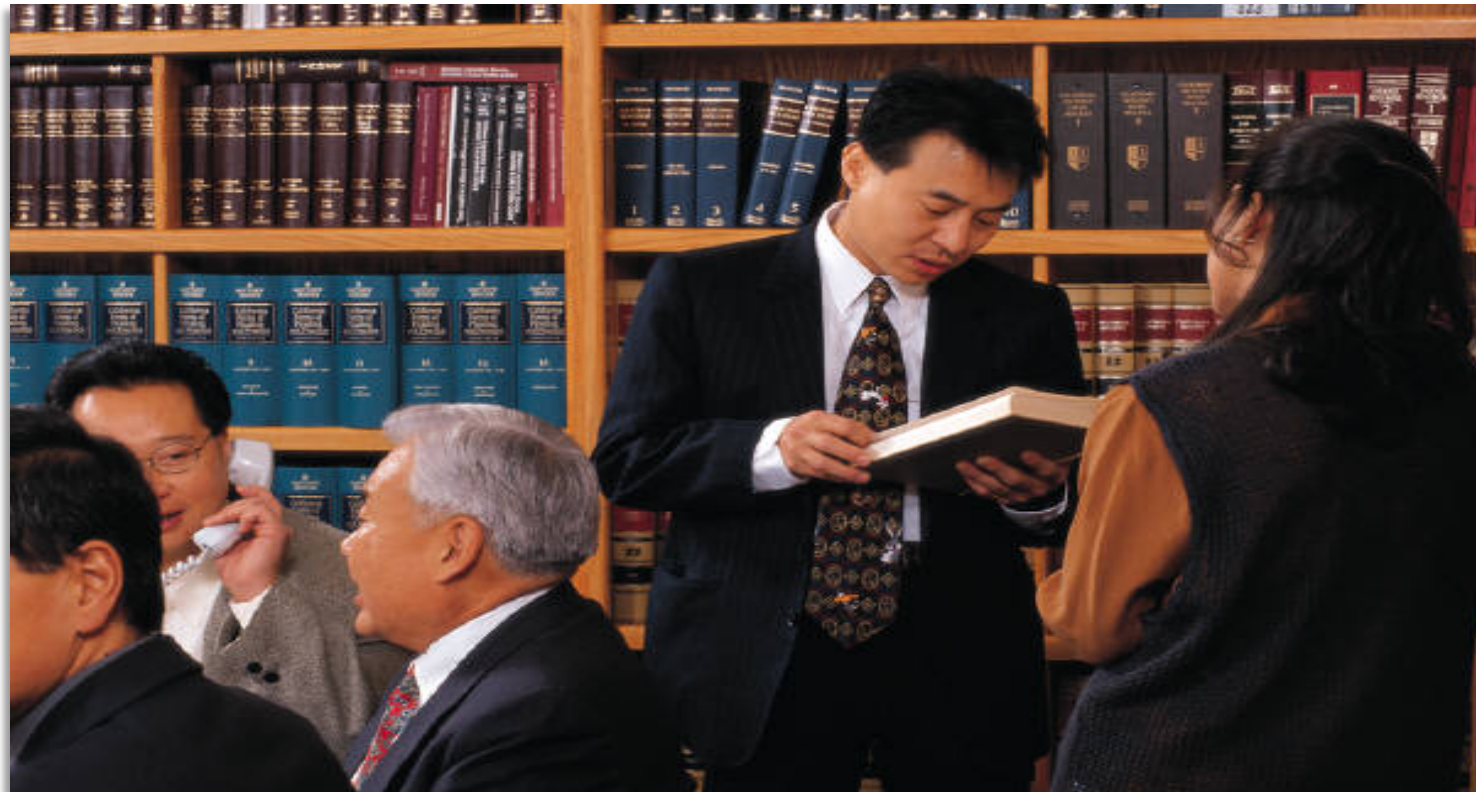
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KNOW THE RULES





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1. LEGISLATIVE GUIDANCE

- Statutory Law

<http://thomas.loc.gov>

- Small Business Act (Public Law 85-536, as amended)

http://www.sba.gov/sites/default/files/tool_serv_sbact.pdf





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2. REGULATORY GUIDANCE

Title 13 of the United States Code of Federal Regulations (13 CFR)

- Section 121 – SB Size Regulations
- Section 124 – 8(a) BD/SDB Programs
- Section 125 – Subcontracting
 - – Limitations on Subcontracting
 - – SDVOSB Program
- Section 126 – HUBZone Program
- Section 127 – WOSB Program
- Section 134 – Appeal Procedures
- <http://ecfr.gpoaccess.gov>





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3. RECENT GUIDANCE

- Small Business Jobs Act of 2010
- National Defense Authorization Act of 2013
- National Defense Authorization Act of 2015
- WOSB Sole Source Program FAR 19.1506





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TOP TEN BEST PRACTICES

- Know Organization's Points of Contact
- Understand FDA's Mission and Needs
- Know FDA's SB Goals and Top NAICS codes
- Research Research Research
 - Budget and Brief
 - Procurement Forecast
 - FPDS and USA Spending
- Understand Strategic Sourcing, Internal IDIQs, GWACs





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TOP TEN BEST PRACTICES

- Pursue Grants
- Create Targeted Marketing Tools
- Respond to Sources Sought Notices
- Network
 - VOS
 - Industry Days
 - Trade Associations
- Know the Rules





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**BE PREPARED WHEN
OPPORTUNITY KNOCKS!**





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OSDBU CONTACT

**200 Independence Avenue, SW
Room 537
Washington, DC 20201**

Website: www.hhs.gov/smallbusiness

Phone: 202.690.7300

Email: sbmail@hhs.gov





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<http://www.youtube.com/user/HHSOSDBU>





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