

**The Jordanian Association of Pharmaceutical Manufacturers (JAPM)
Request For Quotes (RFQ) No. 1-2016
eCTD systems group buying for six pharmaceutical companies**

Issue Date: 10/04/2016

1. Synopsis of the Request for Quotation

JAPM, implementer of the eCTD group buying project for six pharmaceutical manufacturers , invites qualified vendors to submit quotations to supply ,deliver, install, activate and provide training for proper use for six eCTD systems for ten users in six different sites as follows:

1. RFQ No.	RFQ No.1-2016
2. Issue Date	10 th of April 2016
3. Title	eCTD systems group buying for six pharmaceutical companies
4. Issuing Office & Email/Physical Address for Submission of Quotes	The Jordanian Association of Pharmaceutical Manufacturers (JAPM) Yazan Aranki Street Villa No. 1 Amman, Jordan Tel: +962 6 541 3114 Fax: +962 6 541 3116 Mobile: +962 79 526 5361 Email: hanan@japm.com
5. Deadline for Receipt of Quotes.	23 rd of April 2016
6. Point of Contact	dana@japm.com
7. Anticipated Award Type	Firm Fixed Price Purchase Order Issuance of this RFQ in no way obligates JAPM to award a subcontract or purchase order and Bidders will not be reimbursed for any costs associated with the preparation of their quote.
8. Basis for Award	An award will be made to the responsible bidder whose bid is responsive to the terms of the RFQ and is most advantageous to JAPM, considering price or/and other factors included in the RFQ. To be considered for award, bidders must meet the requirements identified in Section 12, "Determination of Responsibility". No discussions or negotiations are permitted with bidders, and therefore bidders shall submit their best and final price.

Interested Bidders may obtain a full copy of the RFQ which contains detailed instructions for preparation of the quote. The RFQ may be collected from the address and/or contact person above.

2. Request for Quotation

<p>9. General Instructions to Bidders</p>	<ul style="list-style-type: none"> • The final date for receiving solicitation responses will be the 20th of April 2016 at 12:00 noon Jordan's time. Late offers will be rejected except under extraordinary circumstances at JAPM's discretion. • Bidders shall submit quotes electronically via procurement e-mail "hanan@japm.com". • Include a statement that the vendor fully understands that their quote must be valid for a period of 120 days. • Bidders shall sign and date their quotation. • Bidders shall complete Attachment A: Price Schedule template. Value Added Tax (VAT) shall be included on a separate line. • These services are not eligible for international VAT exemption.
<p>10. Questions Regarding the RFQ</p>	<p>Each Bidder is responsible for reading very carefully and understanding fully the terms and conditions of this RFQ. All communications regarding this solicitation are to be made solely through the Issuing Office and must be submitted via email or in writing delivered to the Issuing Office no later than the date specified above. All questions received will be compiled and answered in writing and distributed to all interested Bidders.</p>
<p>11. Technical Specifications and requirements for Technical Acceptability</p>	<ol style="list-style-type: none"> 1. A detailed list of technical specifications for the eCTD systems to be provided are found in Attachment B. 2. Complete Installation is required by the 1st of May 2016.
<p>12. Determination of Responsibility</p>	<p>JAPM will not enter into any type of agreement with a vendor prior to ensuring the vendor's responsibility. When assessing a vendor's responsibility, the following factors are taken into consideration:</p> <ol style="list-style-type: none"> 1. Provide copies of the required business licenses to operate in the host country. 2. Evidence of a DUNS number (explained below and instructions contained in the Annex). 3. The source, origin and nationality of the services are not from a Prohibited Country (explained below). 4. Ability to comply with required or proposed delivery or performance schedules, vendors are required to propose delivery or performance schedules.
<p>13. Geographic Code</p>	<ul style="list-style-type: none"> • Under the authorized geographic code for JAPM for the purposes of this RFQ only, JAPM may only procure goods and services from the following countries. • Geographic Code 937: Goods and services from the United States, the cooperating country, and "Developing Countries" other than "Advanced Developing Countries";, excluding prohibited countries. A list of the "Developing Countries" as

	<p>well as "Advanced Developing Countries" can be found in the attached PDF.1 and PDF.2, respectively.</p> <ul style="list-style-type: none"> • JAPM must verify the source, nationality and origin, of goods and services and ensure (to the fullest extent possible) that JAPM does not procure any services from prohibited countries listed by the Office of Foreign Assets Control (OFAC) as sanctioned countries. The current list of countries under comprehensive sanctions include: Cuba, Iran, North Korea, Sudan, and Syria. • By submitting a quote in response to this RFQ, Bidders confirm that they are not violating the Source and Nationality requirements and that the services comply with the Geographic Code and the exclusions for prohibited countries.
14. Data Universal Numbering System (DUNS)	<p>All U.S. and foreign organizations which receive first-tier subcontracts/ purchase orders with a value of \$25,000 and above are required to obtain a DUNS number prior to signing of the agreement. Organizations are exempt from this requirement if the gross income received from all sources in the previous tax year was under \$300,000. JAPM requires that Bidders sign the self-certification statement if the Bidder claims exemption for this reason.</p> <p>For those required to obtain a DUNS number, you may request Attachment C: Instructions for Obtaining a DUNS Number. For those not required to obtain a DUNS number, you may request Attachment D: Self-Certification for Exemption from DUNS Requirement</p>
15. Compliance with Terms and Conditions	Bidder shall be aware of the general terms and conditions for an award resulting from this RFQ.
16. Procurement Ethics	By submitting a Bidder, Bidders certify that they have not/will not attempt to bribe or make any payments to JAPM employees in return for preference, nor have any payments with Terrorists, or groups supporting Terrorists, been attempted. Any such practice constitutes an unethical, illegal, and corrupt practice.

1.1 Attachment A: Price Schedule

Item Number	Item Name	Quantity*	Unit Price	Total
1	eCTD System to cover all kinds of license types in a single license: EU/AU/NZ/GCC Nees, EU/CH/US/CA/GC/ZA/AU/TH eCTD, EU VNees	1		
2	Live Web training, Email/VOIP support			
3	Regular updates to eCTD Systems (new versions)			
4	Additional on-site training/workshop			
5	License Renewal Fees (after 2 years)			
6	Discount rate, if applicable			
7	VAT			
GRAND TOTAL IN UNITED STATES DOLLARS**			\$	

*Total required licenses are ten (10) for six (6) eCTD systems in six (6) different sites.

**Please provide the exchange rate used, if applicable.

Payment Schedule

Installment No.	Installment	Installment Percentage
1	Upon issuing the Firm Fixed Purchase Order	15%
2	Upon Installation of the eCTD Systems	35%
3	Upon completion of one on one training for all users	15%
4	Upon final activation	35%

We, the undersigned, provide the attached quote in accordance RFQ # _____ dated _____ Our attached quote is for the total price of _____ (figure and in words)

I certify a validity period of ___ days for the prices provided in the attached Price Schedule/Bill of Quantities. Our quote shall be binding upon us subject to the modifications.

We understand that JAPM is not bound to accept any quotes it receives.

Authorized Signature:

Name and Title of Signatory:

Name of Firm:

Address:

Telephone:

Email:

Company Seal/Stamp:

1.2 Attachment B: Detailed Technical Specifications

Characteristics of the eCTD systems (all characteristics should apply to all ten (10) licenses)

Vendors should ensure that various tools included in the package to ensure that the work continues flawlessly, should include but not limited to:

- Compilers/Publishers [per each license]: US (FDA) eCTD, CA (HCSC) eCTD, EU eCTD, EU NeeS, EU VNeS, CH (Swissmedic) eCTD, GCC (SFDA) eCTD and NeeS, ZA (MCC) eCTD, AU (TGA) / NZ (Medsafe) NeeS, AU (TGA) eCTD, TH (FDA) eCTD.
- Each license is per computer (concurrent user counts as one license) per year.
- Licenses should be valid for 2 years from activation date.

- eCTD systems to be regularly updated in the light of changes in the FDA / SFDA / HCSC / TGA / Swissmedic / EMEA / MCC, ICH eCTD/NeS specification.
- PDF Virtual Printer.
- pCTD Compiler / paper publishing*.
- eCTD Lifecycle Viewer.
- Submission Comparer
- PDF Hyperlink Fixer
- Templated Compiler (+pCTD -> any region supporting paper submissions)
- Document Manager
- Compatible with the systems of the related regulatory agencies and other service providers.
- User friendly and covers of needs of the companies.
- Submissions published using eCTD Office conform to the rules and best practices following eCTD/NeS/VNeS Specifications.
- Submissions to multiple markets should be allowed to be done smoothly through the system.

* The requirements for electronic versus paper submissions depend on the market. Some of our markets require only eCTD submission like KSA and Oman so far. Other markets still accept paper CTD files and or electronic copies of CTD files (non eCTD). Companies will need to be able to create non eCTD electronic copies in addition to paper copies out of the new eCTD software.

1.3.2 Licenses Required:

Users of the new eCTD system are the Regulatory Affairs department and IT department employees.

- Total number of licenses required is ten (10) licenses to include all types of needed eCTD in one single license. Compilers/Publishers [per each license] should include: US (FDA) eCTD, CA (HCSC) eCTD, EU eCTD, EU NeeS, EU VNeS, CH (Swissmedic) eCTD, GCC (SFDA) eCTD and NeeS, ZA (MCC) eCTD, AU (TGA) / NZ (Medsafe) NeeS, AU (TGA) eCTD, TH (FDA) eCTD.
- License is counted per user.
- Total number of users required is ten (10) users.

- Total number of sites for local installation of the eCTD system is six (6) pharmaceutical companies.

1.3.3 The Life cycle management properties of the new eCTD system

The below points need to be discussed and coordinated between the company and the vendor

- Building up the system and migrating legacy data into this system, as appropriate.
- Training of users and roll-out into the organization.
- Maintenance plan of the system (training and SOPs for technical staff etc.)
- An update-strategy must be in place (i.e. retirement of the old system and replacement by a new one).

1.3.4 Minimum Hardware Requirements

Based on the six companies current capabilities, the minimum hardware requirements that the system should match are the following:

Hardware Component	Minimum Requirement
CPU Single Core	1 GHz Multi Core
RAM Memory	2 GB
Video Resolution	1024 x 768 (4:3)
Free Disk Space for Installation	20 MB

Otherwise, the vendor should identify the extra hardware requirements needed to ensure successful and smooth flow and use of the eCTD systems.

1.3.5 Platform Requirements

The vendor should identify a list of Pre-requirements for implementing eCTD at the different sites, including but not limited to:

- System installation specific configuration
- Installation of needed programs/applications (e.g Acrobat Professional, Acrobat Reader) with the correct versions
- System performance: Network/Internet improvement, download and upload capacities
- Is DMS (Data Management System) required?

1.3.6 Users and Training

- A minimum of one on one training to be provided by the vendor; provided that the software is fully functional and activated.
- Preparation of Users Manuals.
- Vendor should specify the training if online or on-site.
- Training concept, training material, and roll-out-plan should be provided by the vendor and training should be completed before the go-live of the system.

1.3.7 After Sales Service

- Vendors should specify their after sales service methods and requirements.
- If there is any embedded cost, it should be added to the Price Schedule in Attachment A.

1.3.8 Update & Maintenance

The vendor will be responsible for the update and maintenance of the eCTD software according to the contractual agreement between parties, maintenance license should be valid for at least two years from the activation date

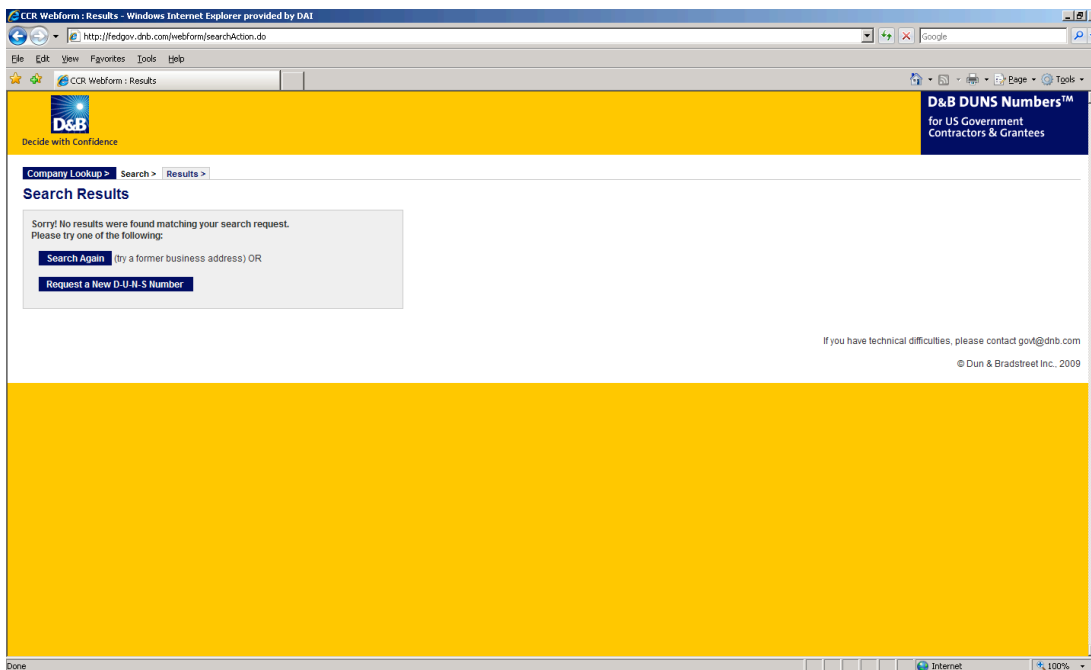
1.3 Attachment C: Instructions for Obtaining a DUNS number

1. Log on to the D&B (Dun & Bradstreet) DUNS registration website to begin the process of obtaining a DUNS number free of charge.

<http://fedgov.dnb.com/webform/index.jsp>

Please note there is a bar on the left for Frequently Asked Questions as well as emails and telephone numbers for persons at Dun & Bradstreet for you to contact if you have any questions or difficulties completing the application on-line. JAPM is not authorized to complete the application on your organization's behalf; the required data must be entered by an authorized official of your organization.

2. Select the Country where your company is physically located.
3. You will first be asked to search the existing DUNS database to see whether a DUNS number already exists for your organization/entity. Subcontractors/grantees who already have a DUNS number may verify/update their DUNS records.
4. Potential JAPM subcontractors/vendors/grantees who do not already have a DUNS number will be shown the screen below. To request a new DUNS Number, the "Request a New D-U-N-S Number" button needs to be selected.



5. Enter the information regarding your organization listed on the next three screens. (See screen shots below.) Make sure you have the following information available (in English) prior to beginning the process of entering this section in order to ensure successful registration.

- Legal Business Name (commas are allowed, periods are not allowed)
- Address
- Phone
- Name of Owner/Executive
- Total Number of Employees
- Annual Sales or Revenue (US Dollar equivalent)
- Description of Operations

6. Note that some fields are Optional, however all other fields must be completed to proceed further with the application process. For example, all applicants must complete the Organization Information sections. The Company Name and Physical Address fields are self-populated based on information previously entered during the initial DUNS search. The question marks to the left of the field provide additional information when you click on them.

The screenshot shows a web browser window titled "CCR Webform : New Duns Number Request." The URL is "http://fedgov.dnb.com/webform/newReq.do?hdnCompanyNumber=1&brower=&hdnCompanyName=&hdnAddress=&hdnCity=&hdnState=&hdnZip=&hdnCountry=&hdnDuns=&hdnTradeStyleName=&newComp=". The page header includes the D&B logo and "D&B DUNS Numbers™ for US Government Contractors & Grantees". The main heading is "Request for New D-U-N-S Number". Below this, there is a note: "Any affiliated companies at the same address, will not be affected. If there are affiliated companies at the same address, please specify in the Notes section." and "Complete the information below to obtain a new D-U-N-S Number for your company's physical location." A sub-note states: "Note: All fields are required unless otherwise indicated." The form is divided into sections: "Company Name" with fields for Legal Name (DNB TEST, INCI), Legal Structure (Proprietorship), Tradestyle Name 1 (optional), Tradestyle Name 2, Tradestyle Name 3, and Phone Number of Business (20-555-1212). "Physical Address" fields include Street (100 Jalan Abdul Rahman), City (Kabul), State, Zip Code + 4/Postal Code, and Country (AFGHANISTAN). "Mailing Address (optional)" has a checkbox for "Same as Physical Address" and fields for Street/ P.O. Box and City.

7. You must select the legal structure of your organization from the pull down menu. To assist you in selecting the appropriate structure that best represents your organization, a brief description of the various types follows:

- **Corporation** – A firm that meets certain legal requirements to be chartered by the state/province in which it is headquartered by the filing of articles of incorporation. A corporation is considered by law to be an entity separate and distinct from its owners. It can be taxed; it can be sued; it can enter into contractual agreements.
- **Government** - central, province/state, district, municipal and other U.S. or local government entities. Includes universities, schools and vocational centers owned and operated by the government.
- **Limited Liability Company (LLC)** - This is a type of business ownership combining several features of corporation and partnership structures. It is designed to provide the limited liability features of a corporation and the tax efficiencies and operational flexibility of a partnership. Its owners have limited personal liability for the LLC's debts and obligations, similar to the status of shareholders in a corporation. If your firm is an LLC, this will be noted on the organizations registration and licensing documents.
- **Non-profit** - An entity which exists for charitable reasons and is not conducted or maintained for the purpose of making a profit. Any money earned must be retained by the organization, and used for its own expenses, operations, and programs. Most organizations which are registered in the host country as a non-governmental organization (NGO) rather than as a commercial business are non-profit entities.

Community based organizations, trade associations, community development councils, and similar entities which are not organized as a profit making organization should select this status, even if your organization is not registered formally in country as an NGO.

- **Partnership**- a legal form of operation in which two or more individuals carry on a continuing business for profit as co-owners. The profits and losses are shared proportionally.
 - **Proprietorship**-These firms are owned by one person, usually the individual who has day-to-day responsibility for running the business. Sole proprietors own all the assets of the business and the profits generated by it.
8. One of the most important fields that must be filled in is the Primary SIC code field. (See screen shot below.) The Primary Standard Industrial Code classifies the business' most relevant industry and function.

CCR Webform: New Duns Number Request - Windows Internet Explorer provided by DAI

http://fedgov.dnb.com/webform/newReq.do?hdnCompanyNumber=1&browser=&hdnCompanyName=&hdnAddress=&hdnCity=&hdnState=&hdnZip=&hdnCountry=&hdnDuns=&hdnTradeStyleName=&newComp=

File Edit View Favorites Tools Help

CCR Webform: New Duns Number Request.

Street/ P.O. Box

City

State

Zip Code + 4/Postal Code

Country

Organization Information

Executive Name

Title

Primary SIC code

Description of Operations

Socioeconomic Data

Number of Employees(includes owners, partners, and/or officers)

Annual Sales or Revenue

Parent Organization (optional)

Name

Street

City

State

Zip Code + 4/Postal Code

Country

Notes (optional)

If you have technical difficulties, please contact gov@dnb.com

Done

9. If you are unsure of which SIC Code your organization's core business falls under, please refer to the following website: <http://www.osha.gov/oshstats/sicser.html>

Standard Industrial Classification (SIC) System Search - Windows Internet Explorer provided by DAI

http://www.osha.gov/pls/ins/sicsearch.html

File Edit View Favorites Tools Help

Standard Industrial Classification (SIC) System Search

UNITED STATES DEPARTMENT OF LABOR

OSHA

Occupational Safety & Health Administration We Can Help

Home Workers Regulations Enforcement Data & Statistics Training Publications Newsroom Small Business OSHA

STATISTICS & DATA | SIC MANUAL

This page allows the user to search the 1987 version SIC manual by keyword, to access descriptive information for a specified 2,3,4-digit SIC, and to examine the manual structure.

Enter a SIC CODE:

Enter the search keyword(s):

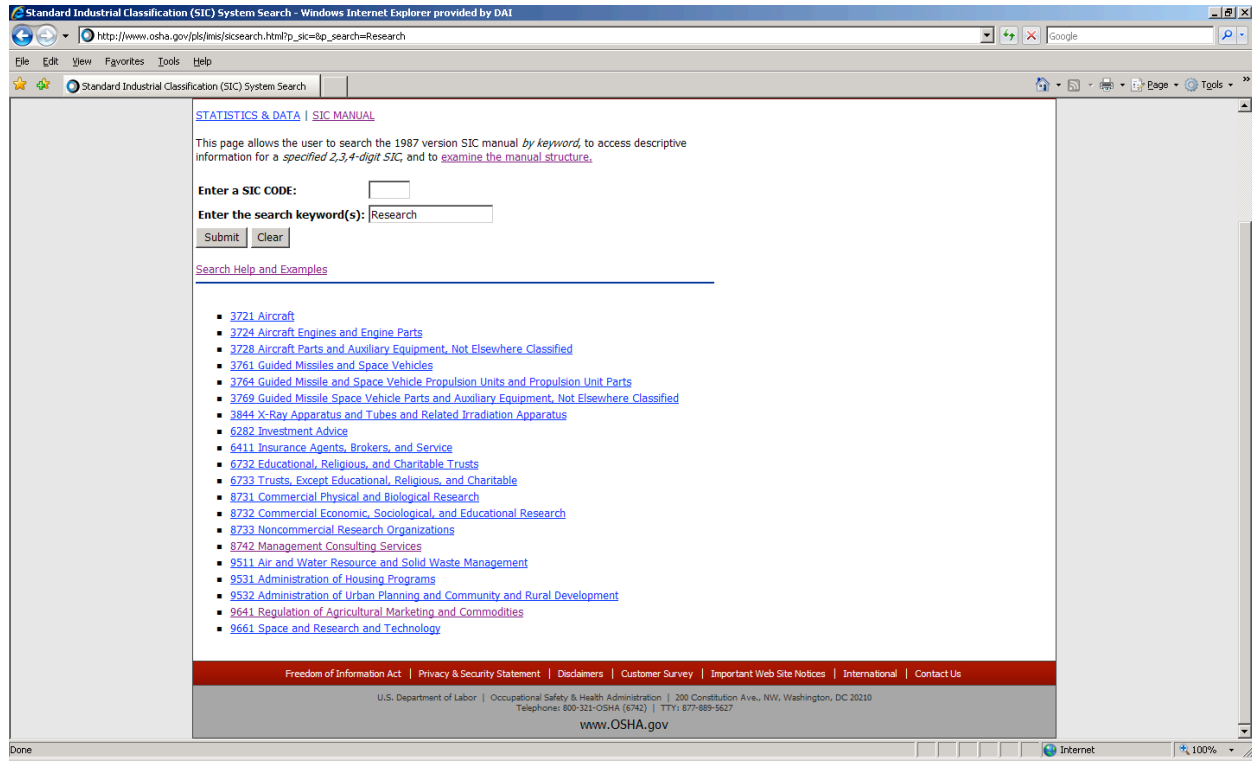
[Search Help and Examples](#)

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Telephone: 800-321-OSHA (6742) | TTY: 877-889-5627
www.OSHA.gov

Internet 100%

You will need to enter certain keywords to bring up the potential SIC Codes. In the case above, “Research” was entered as the keyword, and resulted in the following:



PLEASE NOTE: Many of the JAPM subcontractors and grantees fall under one of the following SIC codes:

8742 Management Consulting Services

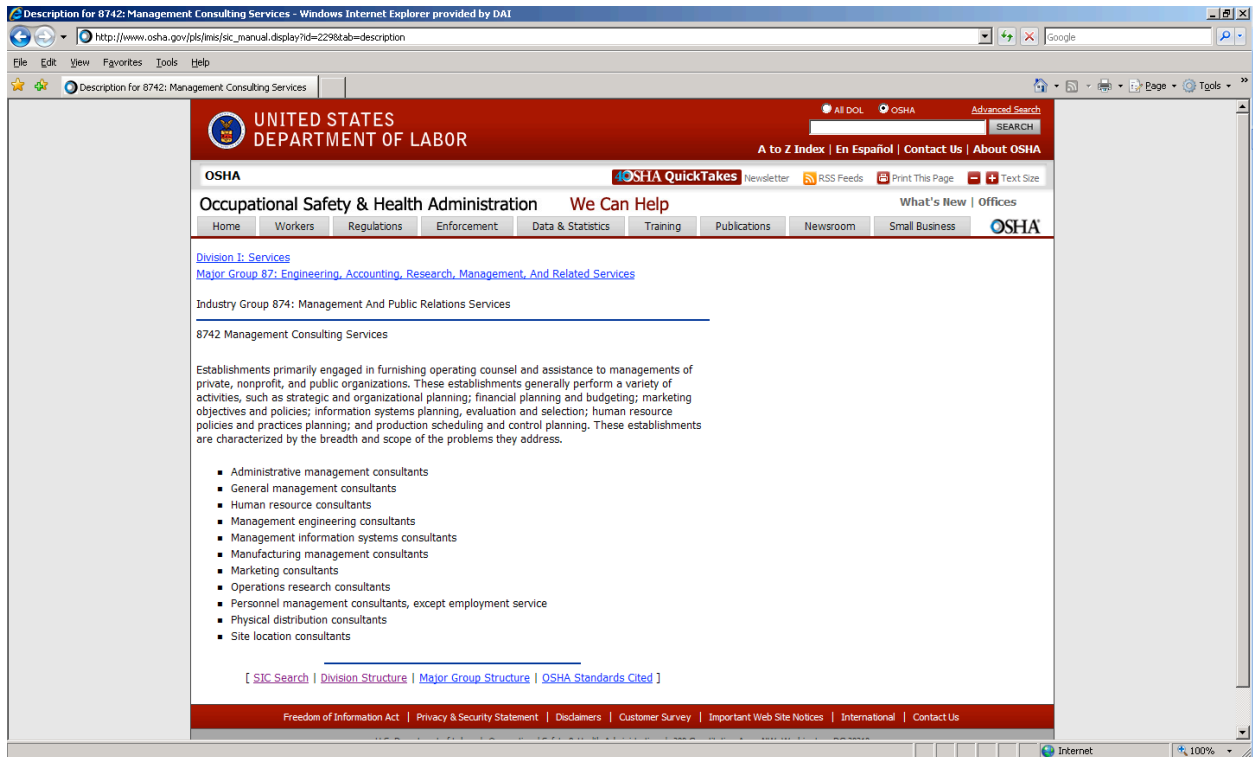
1542 General Contractors-Nonresidential Buildings, Other than Industrial Buildings and Warehouses or one of the codes within:

Industry Group 357: Computer And Office Equipment

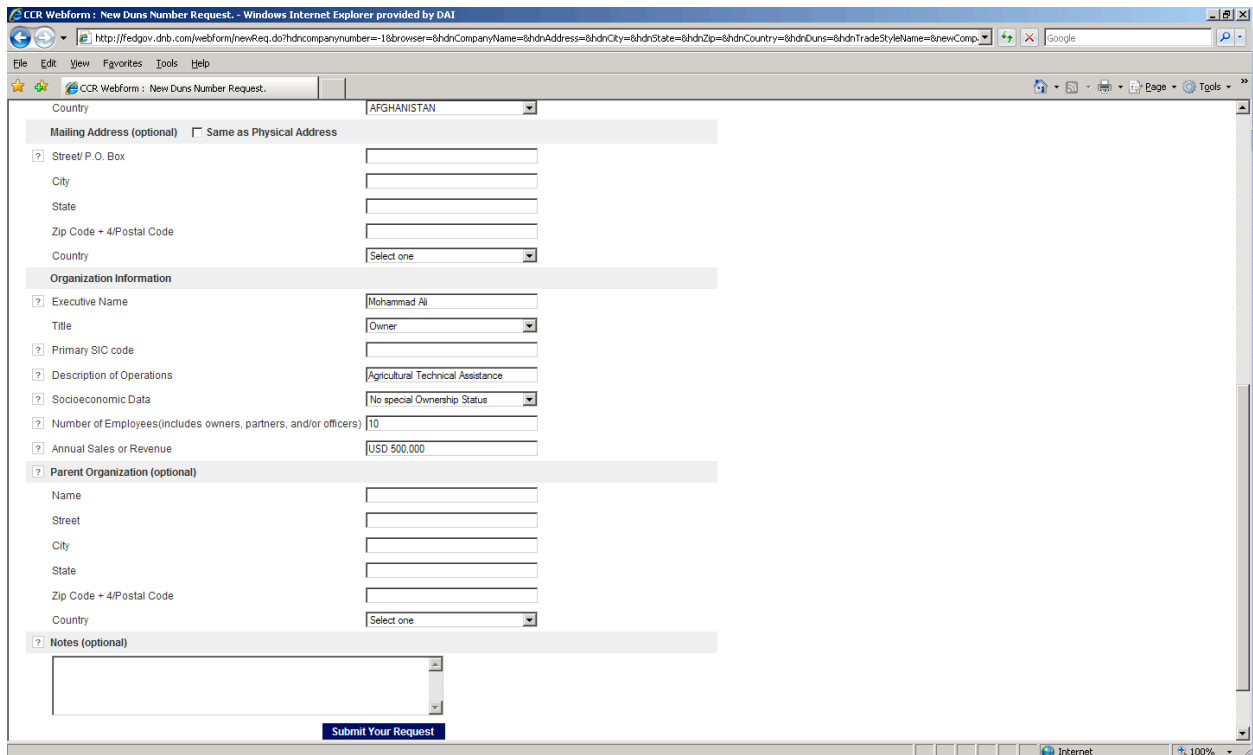
Industry Group 355: Special Industry Machinery, Except Metalworking

Industry Group 356: General Industrial Machinery And Equipment

Industry Group 359: Miscellaneous Industrial And Commercial



10. Description of Operations- Enter a brief description of the primary services you provide the example below, “agricultural technical assistance” was chosen as the primary function of the business.



11. The Annual Sales or Revenue figure should be provided in USD (US Dollar) equivalent.
12. Once all of the fields have been completed, click on “Submit Your Request” to be taken to the Verification page.
13. Note: Representative (Principal, Owner or Officer) needs to verify and provide affirmation regarding the accuracy of the data under criminal or civil penalties as per Title 18, Section 1001 of the US Criminal Code.
14. Once “Yes, Continue” button is clicked, the registration application is sent to D&B, and a DUNS number should be available within 24-48 hours. DUNS database can be checked in 24-48 hours by entering the Business Information in the Search window – which should now display a valid result with the new DUNS number for the entity.

CCR Webform : verification page - Windows Internet Explorer provided by DAI

http://fedgov.dnb.com/webform/NewDunsRequest.do

File Edit View Favorites Tools Help

CCR Webform : verification page

D&B DUNS Numbers™
for US Government
Contractors & Grantees

D-U-N-S Number Request > Search > Enter Your Company Information > Verify Information Page >

Verification Page

Company Name

Legal Name: DNB TEST, INC

Phone Number of Business: 20.555-1212

Physical Address

Street: 100 Jalan Abdul Rahman

City: Kabul

State:

Zip Code + 4/Postal Code:

Country: AFGHANISTAN

Organization Information

Executive Name: Mohammad Ali

You affirm that you are a principal, owner or officer of the entity for which you are submitting proposed information and/or changes and that you are properly authorized to submit these changes. You also agree not to knowingly provide any false or misleading information to D&B. Knowingly providing false or misleading information may result in criminal or civil penalties as per [Title 18, Section 1001 of the US Criminal Code](#), and may negatively impact the status of the D&B report maintained on this company.

This also includes the use of a Shelf Corporation. D&B defines a Shelf Corporation as one that exhibits either of the following characteristics: (1) An aged corporation where no prior business activities could be confirmed or (2) An aged corporation that was revoked, dissolved or went to a dormant status, and is subsequently reinstated and is under new control. It is D&B's policy that the historical business activity of a Shelf Corporation, if any, will not be factored into the determination of such Shelf Corporation's start date. As such, any individual who attempts to misrepresent the start date of their business through the use of a Shelf Corporation or any other means is immediately put on information alert status or higher-risk status. In addition, the criminal penalties mentioned above may apply.

Done Internet 100%

1.4 Attachment D: Self Certification for Exemption from DUNS Requirement

Self-Certification for Exemption from DUNS Requirement

For Subcontractors and Vendors

Legal Business Name:

Physical Address:

Physical City:

Physical Foreign Province (if applicable):

Physical Country:

Signature of Certifier

Full Name of Certifier (Last Name, First/Middle Names):

Title of Certifier:

Date of Certification (mm/dd/yyyy):

The sub-contractor/vendor whose legal business name is provided herein, certifies that we are an organization exempt from obtaining a DUNS number, as the gross income received from all sources in the previous tax year is under USD \$300,000.

*By submitting this certification, the certifier attests to the accuracy of the representations and certifications contained herein. The certifier understands that s/he and/or the sub-contractor/vendor may be subject to penalties, if s/he misrepresents the sub-contractor/vendor in any of the representations or certifications to the Prime Contractor and/or the US Government.

The sub-contractor/vendor agrees to allow the Prime Contractor and/or the US Government to verify the company name, physical address, or other information provided herein. Certification validity is for one year from the date of certification.