

U.S. GOVERNMENT PRINTING OFFICE

Washington, DC

GENERAL TERMS, CONDITIONS, AND SPECIFICATIONS

For the Procurement of

FDA Drug Folders

as requisitioned from the U.S. Government Printing Office (GPO) by the

Department of HHS/FDA

Single Award

TERM OF CONTRACT: The term of this contract is for the period beginning date of award and ending August 31, 2015, plus up to four (4) optional 12-month extension periods that may be added in accordance with the "Option to Extend the Term of the Contract" clause in Section 1 of this contract.

BID OPENING: Bids shall be publicly opened at 11 a.m., prevailing Washington, D.C. time, on October 30, 2014.

BID SUBMISSION: Submit bid in pre-addressed envelope furnished with solicitation or send to: U.S. Government Printing Office, Bid Section, Room C-831, Stop: PPSB, 732 North Capitol Street, NW, Washington, DC 20401. Facsimile bids in response to this solicitation are permitted. Facsimile bids may be submitted directly to the GPO Bid Section, Fax No. (202) 512-1782. The program number and bid opening date must be specified with the bid. Refer to Facsimile Bids in Solicitation Provisions of GPO Contract Terms, GPO Publication 310.2, as revised June 2001. Hand delivered bids are to be taken to: The GPO Bookstore, 710 North Capitol Street, NW, Washington, DC between the hours of 8:00 a.m. and 4:00 p.m. on business days and follow the instructions in the Bid Submission/Opening area. If further instruction or assistance is required, call (202) 512-0526.

BIDDERS, PLEASE NOTE: These specifications have been revised; therefore, all bidders are cautioned to familiarize themselves with all provisions of these specifications before bidding.

Abstracts of contract prices are available at <http://www.gpo.gov/gpo/abstracts/abstract.action?region=central>.

For information of a technical nature call Kevin Hodges (202) 512-1164 (No collect calls) or aps-Team3@gpo.gov.

SECTION 1.- GENERAL TERMS AND CONDITIONS

GPO CONTRACT TERMS: Any contract which results from this Invitation for Bid will be subject to the applicable provisions, clauses, and supplemental specifications of GPO Contract Terms (GPO Pub. 310.2, effective December 1, 1987 (Rev. 6-01)) and GPO Contract Terms, Quality Assurance Through Attributes Program for printing and binding (GPO Pub. 310.1, effective May 1979 (revised August 2002)).

GPO Contract Terms (GPO Publication 310.2) – <http://www.gpo.gov/pdfs/vendors/sfas/terms.pdf>.

GPO QATAP (GPO Publication 310.1) – <http://www.gpo.gov/pdfs/vendors/sfas/qatap.pdf>.

DISPUTES: GPO Publication 310.2, GPO Contract Terms, Contract Clause 5. Disputes, is hereby replaced with the June 2008 clause found at www.gpo.gov/pdfs/vendors/contractdisputes.pdf. This June 2008 clause also cancels and supersedes any other disputes language currently included in existing contractual actions.

QUALITY ASSURANCE LEVELS AND STANDARDS: The following levels and standards shall apply to these specifications:

Product Quality Levels:

- (a) Printing (page related) Attributes -- Level IV.
- (b) Finishing (item related) Attributes -- Level IV.

Inspection Levels (from ANSI/ASQC Z1.4):

- (a) Non-destructive Tests - General Inspection Level I.
- (b) Destructive Tests -- Special Inspection Level S-2.

Specified Standards: The specified standards for the attributes requiring them shall be:

<u>Attribute</u>	<u>Specified Standard</u>
P-7. Type Quality and Uniformity	Camera Copy

EXTENSION OF CONTRACT TERM: At the request of the Government, the term of any contract resulting from this solicitation may be extended for such period of time as may be mutually agreeable to the GPO and the contractor.

ASSIGNMENT OF JACKETS, PURCHASE AND PRINT ORDERS: A GPO jacket number will be assigned and a purchase order issued to the contractor to cover work performed. The purchase order will be supplemented by an individual "Print Order" for each job placed with the contractor. The print order, when issued, will indicate the quantity to be produced and any other information pertinent to the particular order.

PREAWARD SURVEY: In order to determine the responsibility of the prime contractor or any subcontractor, the Government reserves the right to conduct a preaward survey or to require other evidence of technical, production, managerial, financial, and similar abilities to perform, prior to the award of a contract.

POSTAWARD CONFERENCE: The total requirements of the product as indicated in these specifications, must be reviewed by Government representatives with the contractor's representatives at Health and Human Services, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, immediately after award.

OPTION TO EXTEND THE TERM OF THE CONTRACT: The Government has the option to extend the term of this contract for a period of 12 months by written notice to the contractor not later than 30 days before the contract expires. If the Government exercises this option, the extended contract shall be considered to include this clause, except, the total duration of the contract may not exceed five years as a result of, and including, any

extension(s) added under this clause. Further extension may be negotiated under the "Extension of Contract Term" clause. See also "Economic Price Adjustment" for authorized pricing adjustment(s).

ECONOMIC PRICE ADJUSTMENT: The pricing under this contract shall be adjusted in accordance with this clause, provided that in no event will any pricing adjustment be made that would exceed the maximum permissible under any law in effect at the time of the adjustment. There will be no adjustment for orders placed during the first period specified below. Pricing will thereafter be eligible for adjustment during the second and any succeeding performance period(s). For each performance period after the first, a percentage figure will be calculated as described below and that figure will be the economic price adjustment for that entire next period. Pricing adjustments under this clause are not applicable to reimbursable postage or transportation costs, or to paper, if paper prices are subject to adjustment by separate clause elsewhere in this contract.

For the purpose of this clause, performance under this contract will be divided into successive periods. The first period will extend from the **beginning of the contract to August 31, 2015**, and the second and any succeeding period(s) will extend for 12 months from the end of the last preceding period, except that the length of the final period may vary. The first day of the second and any succeeding period(s) will be the effective date of the economic price adjustment for that period.

Pricing adjustments in accordance with this clause will be based on changes in the seasonally adjusted "Consumer Price Index For All Urban Consumers - Commodities Less Food" (Index) published monthly in the CPI Detailed Report by the U.S. Department of Labor, Bureau of Labor Statistics.

The economic price adjustment will be the percentage difference between Index averages as specified in this paragraph. An index called the variable index will be calculated by averaging the monthly Indexes from the 12-month interval ending 3 months prior to the beginning of the period being considered for adjustment. This average is then compared to the average of the monthly Indexes for the 12-month interval ending **June 30, 2014**, called the base index. The percentage change (plus or minus) of the variable index from the base index will be the economic price adjustment for the period being considered for adjustment.

The Government will notify the contractor by contract modification specifying the percentage increase or decrease to be applied to invoices for orders placed during the period indicated. The contractor shall apply the percentage increase or decrease against the total price of the invoice less reimbursable postage or transportation costs and separately adjusted paper prices. Payment discounts shall be applied after the invoice price is adjusted.

ORDERING: Items to be furnished under the contract shall be ordered by the issuance of print orders by the Government. Orders may be issued under the contract from September 1, 2014 and ending August 31, 2015 plus for such additional periods as the contract is extended. All print orders issued hereunder are subject to the terms and conditions of the contract. The contract shall control in the event of conflict with any print order. A print order shall be "issued" for purposes of the contract, when it is either deposited in the U.S. Postal Service mail or otherwise furnished to the contractor in conformance with the schedule.

REQUIREMENTS: This is a requirements contract for the items and for the period specified herein. Shipment/delivery of items or performance of work shall be made only as authorized by orders issued in accordance with the clause entitled "Ordering". The quantities of items specified herein are estimates only, and are not purchased hereby. Except as may be otherwise provided in this contract, if the Government's requirements for the items set forth herein do not result in orders in the amounts or quantities described as "estimated", it shall not constitute the basis for an equitable price adjustment under this contract.

Except as otherwise provided in this contract, the Government shall order from the contractor all the items set forth which are required to be purchased by the Government activity identified on page 1.

The Government shall not be required to purchase from the contractor, requirements in excess of the limit on total orders under this contract, if any.

Orders issued during the effective period of this contract and not completed within that time shall be completed by the contractor within the time specified in the order, and the rights and obligations of the contractor and the Government respecting those orders shall be governed by the terms of this contract to the same extent as if completed during the effective period of this contract.

If shipment/delivery of any quantity of an item covered by the contract is required by reason of urgency prior to the earliest date that shipment/delivery may be specified under this contract, and if the contractor will not accept an order providing for the accelerated shipment/delivery, the Government may procure this requirement from another source.

The Government may issue orders which provide for shipment/delivery to or performance at multiple destinations.

Subject to any limitations elsewhere in this contract, the contractor shall furnish to the Government all items set forth herein which are called for by print orders issued in accordance with the "Ordering" clause of this contract.

SECTION 2.- SPECIFICATIONS

SCOPE: These specifications cover the production of high impact linear polyethylene and paper folders requiring such operations as printing, binding, packing, and distribution.

TITLE: FDA Drug Folders.

FREQUENCY OF ORDERS: Approximately 5 to 30 orders per year. An occasional print order may be submitted for both paper and polyethylene folders.

QUANTITY: Approximately 1,000 to 75,000 sets per order. A set shall consist of two pieces (1 front and 1 back).

TRIM SIZES:

Paper Folders: Front folder (flat size) - 10-1/2 x 11-1/2". Back Folder (flat size) - 10-1/2 x 12" (size includes 1/2" lip at top).

Polyethylene Folders: Front folder (flat size) - 9-3/4 x 11-1/2". Back folder (flat size) 9-3/4 x 12". Size includes 1/2" lip at top.

GOVERNMENT TO FURNISH: Camera copy consisting of line art and negatives to be reproduced at various focuses.

A sample to be used for color match of the stock.

One reproduction proof Form 905 (R. 06/03) with labeling and marking specifications.

A supply of blue labels and selection certificates for shipping Departmental Random Copies.

Identification markings such as register marks, ring folios, rubber stamped jacket numbers, commercial identification marks of any kind, etc., except GPO imprint, form number, and revision date, carried on copy or film, must not print on finished product.

CONTRACTOR TO FURNISH: All materials and operations, other than those listed under "Government to Furnish," necessary to produce the products in accordance with these specifications.

STOCK/PAPER: The specifications of all paper furnished must be in accordance with those listed herein or listed for the corresponding JCP Code numbers in the "Government Paper Specification Standards No. 12" dated March 2011.

A copy of the "Government Paper Specification Standards" is available at:
http://www.gpo.gov/pdfs/customers/sfas/vol12/vol_12.pdf.

Color of paper furnished shall be of a uniform shade and a close match by visual inspection of the JCP color sample(s) and/or Pantone number(s). The Contracting Officer reserves the right to reject shipments of any order printed on paper the color of which, in their opinion, materially differs from that of the color sample(s) and/or Pantone number(s) specified.

White Index, grammage basis weight: 140 lbs. per 500 sheets, 25-1/2 x 30-1/2", equal to JCP Code K10.

The contractor may surface tint with full coverage the entire surface of the folders. A sample and the color of stock to be used will be indicated on each print order.

<u>Form No.</u>	<u>Color</u>	<u>Form No.</u>	<u>Color</u>	<u>Form No.</u>	<u>Color</u>
2626a	red	2626e	tan	2626h	maroon
2626b	yellow	2626f	green		
2626c	orange	2675a	green		
2626d	white	2675b	orange		

Polyethylene Folder - High impact linear polyethylene plastic (matte finish or similar). Must withstand temperatures up to 150 degrees Fahrenheit.

The material shall be uniform in color, texture, finish, and other physical properties and shall be free from streaks, blisters, scratches, and mottling. The material shall have a surface smooth enough to allow screen printing with a complete bonding of ink to the surface after a minimum of one hour drying time. The color of ink to be used will be indicated on each print order.

<u>Form No.</u>	<u>Color</u>	<u>Kind</u>	<u>Weight</u>	<u>Ink Color</u>
2626	blue	polyethylene	.023-.025 gauge	black
2675	red	polyethylene	.023-.025 gauge	black
3316	red	polyethylene	.023-.025 gauge	black
3316a	blue	polyethylene	.023-.025 gauge	black
3677v	purple	polyethylene	.023-.025 gauge	black

PRINTING: Printing is required on the face of each folder in a clear, sharp, permanent-type screen printing (for the polyethylene folders) in black ink or a single color other than black. Paper folders may use the printing method of their choice. The color of ink to be used will be indicated on the print order. Up to three orders reverse out of Pantone color. Match Pantone number as indicated on the print order.

Printing must withstand a "Scotch Tape Test", which consists of pressing a strip of "Scotch" tape firmly on the printed area and removing. There should be no transfer of the printed area to the tape.

BINDING/CONSTRUCTION:

Paper Folders: Die-Cut a 1/2 x 1-1/2" section (and remove waste) at the top of the back folder beginning at the left binding edge 1/2" down and extending in 1-1/2", to create a 1/2 x 8-1/4" long lip on the folder. Lip shall extend from the outside edge of the folder 8-1/4". (See exhibit B attached.)

Score front and back folders with 2 scores on each folder along the entire 11-1/2" dimension 3/4" and 1-1/2" in from the left hand binding edge of the folder. The scores must be of a depth to provide a clean straight fold, free from wrinkle when folder is creased and/or folded on the score.

Fold front and back folders along the 3/4" score and fasten folded portion securely to the inside of the folder with a suitable adhesive to create a reinforced hinge for punching.

Punch two 1/4 x 1/16" holes centered in the 11-1/2" dimension, 8-1/2" center to center, center of holes to be 3/8" from the left binding edge of the folder, front and back.

Round corner the inside edge of tab on back folder, and the two outside edges of the front and back folders, or as indicated on print order.

Polyethylene Folders: Die-cut a 1/2 x 1-1/2" section (and remove waste) at the top of the back folder beginning at the left binding edge 1/2" down and extending in 1-1/2", to create a 1/2 x 8-1/4" long lip on the folder. Lip shall extend from the outside edge of the folder 8-1/4". (See exhibit A attached.)

Each piece (front and back) of the folder shall contain an internal hinge formed in the material by heat and pressure, **NOT** by removing a portion of the material or scribing with a pointed instrument. Hinge shall extend along the entire 11-1/2" dimension 3/4" in from the left hand binding edge of the folder. The hinge must be of a depth to provide a clean straight fold, free from wrinkle when folder is creased and/or folded on the hinge, and the folder must remain flat in normal use and must remain closed under its own weight. Hinge created must be capable of withstanding 150,000 flexes without cracking.

Round corner the inside edge of tab on back folder, and the two outside edges of the front and back folders, or as indicated on print order.

Drill 2 round 3/8" diameter holes centered in the 11-1/2" dimension, 8-1/2" center to center on the left binding edge. Center of holes to be 3/8" from the left binding edge. Reinforce both holes with metal eyelets having an opening in the eyelet of 5/16" in diameter and suitable for accomodating an ACCO-type fastener having 1/4" wide prongs.

MARGINS: Margins will be as indicated on the print order or furnished copy.

Gathering: Contractor will be required to assemble all folders into sets (one front and one back). Contractor will not be required to furnish fasteners.

PACKING: If more than one print order is to be delivered at the same time, Contractor will be required to pack by color, 25 sets of folders into suitable inner containers with a maximum weight of 10 pounds per container. Containers are to be one-piece, made of a corrugated material, and sealed with a gummed reinforced tape at the open end of the container. The contents must not shift or move within the container. Containers must be packed and sealed in a manner that will insure acceptance and safe delivery by the U.S. Postal Service. For additional information, refer to page 7 of Contract Terms No. 1, 3. Packing, (i) (1).

Shipping containers shall have a minimum bursting strength of 275 pounds per square inch or a minimum edge crush test (ECT) of 44 pounds per inch width.

Inner containers should then be placed in shipping cartons. Cartons are not to exceed 45-lbs.

Pallets are required for orders delivered to the Laurel Warehouse and must conform to the requirements set forth in Contract Terms No. 1.

LABELING AND MARKING: Reproduce shipping container label from furnished repro, fill in appropriate blanks and attach a label to each carton shipped. Labels must contain the following information; PHS/GPO print order number, form number, the amount contained in each particular box or carton, and the total number of cartons for each order (i.e., box 2 of 10 boxes).

Note: Labels on inner and outer packages must contain the stock number on all Laurel Warehouse quantities.

DEPARTMENTAL RANDOM COPIES (BLUE LABEL): All orders must be divided into equal sublots in accordance with the chart below. A random copy must be selected from each subplot. Do not choose copies from the same general area in each subplot. The contractor will be required to execute a statement furnished by GPO certifying that copies were selected as directed. The random copies constitute a part of the total quantity ordered, and no additional charge will be allowed.

<u>Folders</u>	
<u>Quantity Ordered</u>	<u>Number of Sublots</u>
500 -3,200	50
3,201 - 10,000	80
10,001 - 35,000	125

These randomly selected copies must be packed separately and identified by a special Government-furnished blue label (GPO Form 2678), affixed to each affected container. The container and its contents shall be recorded separately on all shipping documents and sent in accordance with the distribution list or to the largest consignment unless otherwise specified on the print order.

A copy of the PRINT ORDER/SPECIFICATION and a signed Government-furnished certificate of selection, must be included.

DISTRIBUTION: Deliver f.o.b. destination to: Stock: Central Document Room, 5901-B Ammendale Road, Beltsville, MD 20705-1266 (approx. 2,500 to 5,000 copies) and U.S. GPO Public Documents Warehouse, 8660 Cherry Lane, Laurel, MD 20707, Attn: Subscription Stock (approx. 5,000 to 20,000 copies).

Upon completion of each order, all furnished material along with 5 sets of folders shall be returned to: DHHS/PSC/PPS Room 3B-26, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857, 5 sets to: FDA, 12420 Parklawn Dr., Rm 3030, Rockville, MD 20852 Attn: Mia Prather, (301)827-3949. Deliveries to the Parklawn Building are: 8:00 a.m. to 12:00 p.m. – 1:00 p.m. to 4:00 p.m. Deliveries must be made at loading dock.

SCHEDULE: Adherence to this schedule must be maintained. Contractor must not start production of any job prior to receipt of the individual print order (GPO Form 2511). No definite schedule for pickup of material can be predetermined. The contractor will be notified when materials are available.

Furnished material must be picked up from and returned to: DHHS/PSC/PPS Room 3B-26, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857.

The following schedule begins the workday after notification of the availability of print order and furnished material; the workday after notification will be the first workday of the schedule.

Complete delivery must be made with-in 20 workdays.

The ship/deliver date indicated on the print order is the date products ordered for delivery f.o.b. destination must be delivered to the destinations specified.

Unscheduled material such as shipping documents, receipts or instructions, delivery lists, labels, etc., will be furnished with each order or shortly thereafter. In the event such information is not received in due time, the contractor will not be relieved of any responsibility in meeting the shipping schedule because of failure to request such information.

Upon completion of each order, the contractor is to notify the Government Printing Office of the date of shipment (or delivery, if applicable). Call (202) 512-0516 or 0517; callers outside the Washington, D.C. area may call toll free 1-800-424-9470 or 9471.

SECTION 3.- DETERMINATION OF AWARD

The Government will determine the lowest bid by applying the prices offered in the " SCHEDULE OF PRICES" to the following units of production which are the estimated requirements to produce 1 year's production under this contract. These units do not constitute, nor are they to be construed as, a guarantee of the volume of work which may be ordered for a like period of time.

The following item designations correspond to those listed in the " SCHEDULE OF PRICES".

	(1)	(2)
I.(a)	9	1163
(b)	4	850

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SECTION 4.- SCHEDULE OF PRICES

Bids offered are f.o.b. destination to Beltsville, MD and Laurel, MD.

Prices must include the cost of all required materials and operations for each item listed in accordance with these specifications.

Bidder must make an entry in each of the spaces provided. Bids submitted with blank spaces, or with any obliteration, revision, or alteration of the order and manner of submitting bids, may be declared nonresponsive.

An entry of NC (No Charge) shall be entered if bidder intends to furnish individual items at no charge to the Government.

Bids submitted with NB (No Bid) or blank spaces for an item may be declared nonresponsive.

The Contracting Officer reserves the right to reject any offer that contains prices for individual items of production (whether or not such items are included in the Determination of Award) that are inconsistent or unrealistic in regard to other prices in the same offer or to GPO prices for the same operation if such action would be in the best interest of the Government.

All invoices submitted to the GPO shall be based on the most economical method of production.

Fractional parts of 100 will be prorated at the per 100 rate.

I. FOLDERS: Prices offered for items (a) and (b) must be all-inclusive for the production of complete sets of folders (front and back piece) and must include the cost of: stock, printing, constructing the hidden-hinge, drilling, die-cutting, round cornering, and gathering into sets as ordered, and must include the cost of all packing, sealing and distribution in accordance with these specifications.

	<u>Makeready and/or Setup</u> (1)	<u>Running Per 100 Sets</u> (2)
(a) Polyethylene Folderper complete set	\$ _____	\$ _____
(b) Paper Folder.....per complete set	\$ _____	\$ _____

INSTRUCTIONS FOR BID SUBMISSION: Fill out "Section 4.- Schedule of Prices," initialing or signing each page in the space(s) provided. Submit two copies (original and one exact duplicate) of the "Schedule of Prices" with two copies of the GPO Form 910, "BID" form. Do not enter bid prices on GPO Form 910; prices entered in the "Schedule of Prices" will prevail.

Bidder _____

(City - State)

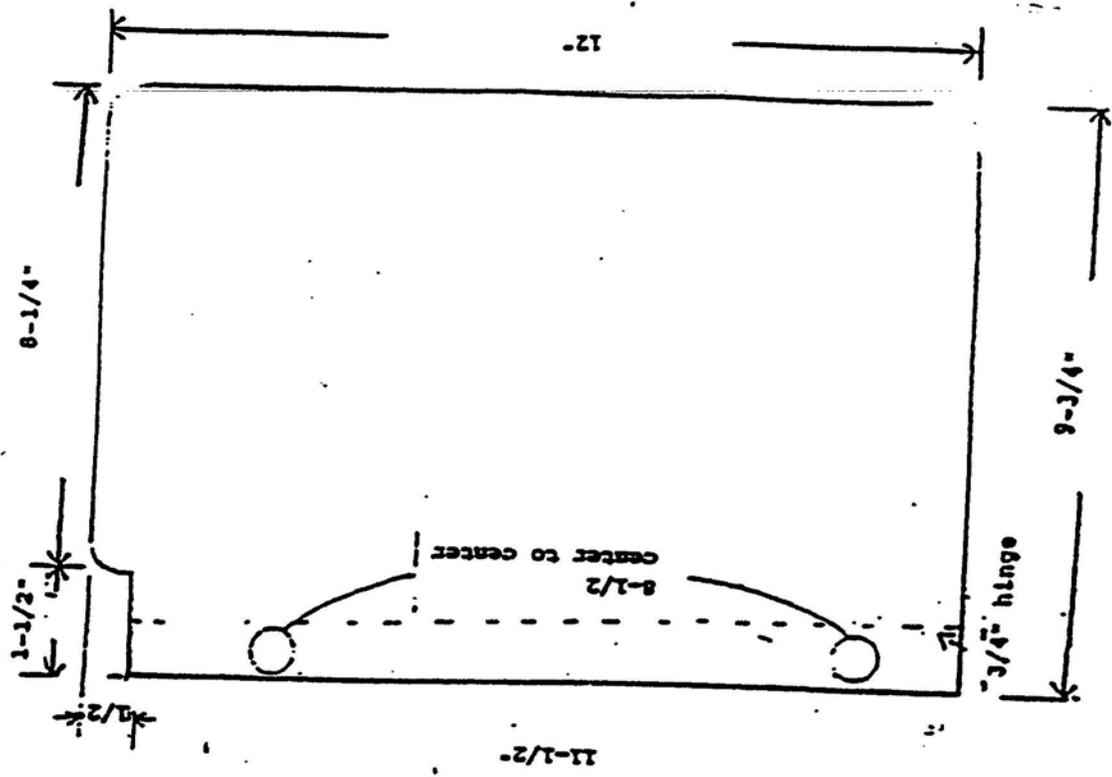
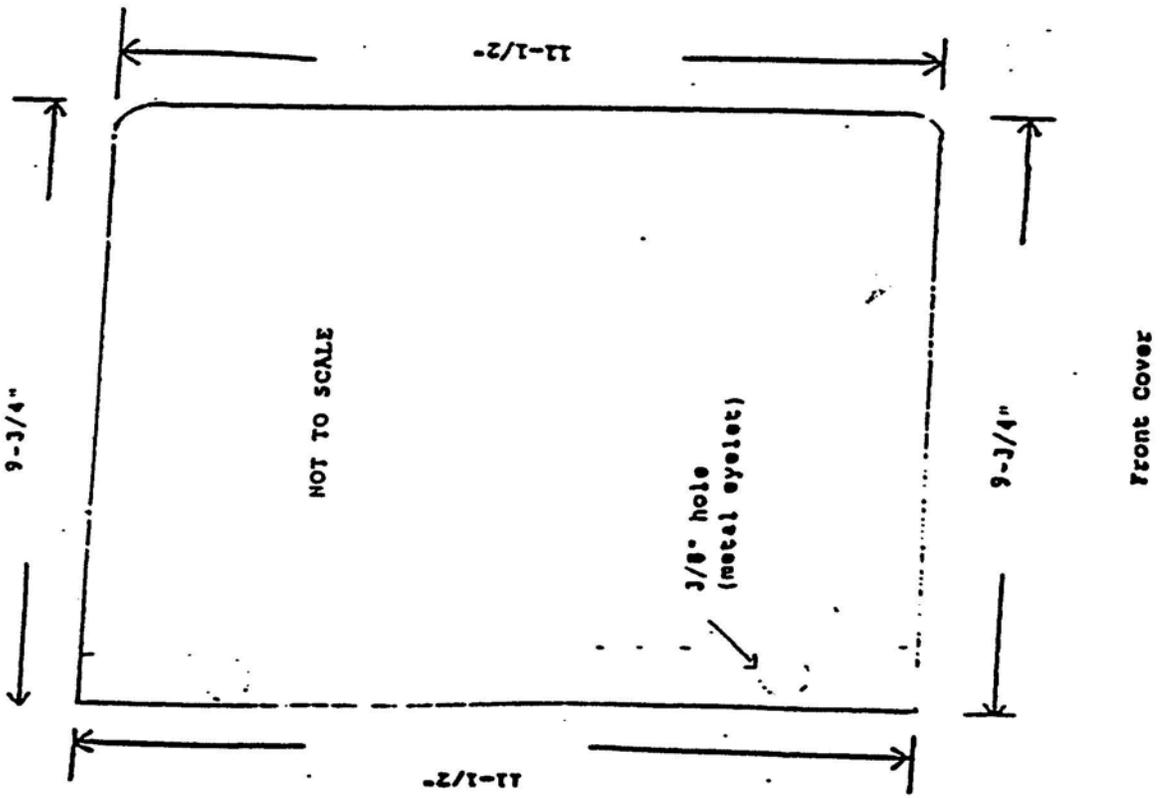
By _____

(Signature and title of person authorized to sign this bid)

(Person to be contacted)

(Telephone Number)

EXHIBIT A



Back Cover

Front Cover

EXHIBIT B

