- 1. How could promotion of products manufactured or distributed by multinational companies be presented on the Internet without violating the act and regulations?
- 2. What factors should FDA consider in determining whether a company is attempting to promote a product within the United States, which is approved for a use in another country, but not so approved in the United States?
- 3. What policies and regulations have other countries established or are considering with respect to the dissemination of information about medical products over the Internet?

FDA welcomes comments on all of the issues described above.

Dated: September 10, 1996. William K. Hubbard, Associate Commissioner for Policy Coordination. [FR Doc. 96–23616 Filed 9–13–96; 8:45 am]

BILLING CODE 4160-01-F

## **Indian Health Service**

Submission for OMB Review; Comment Request, Indian Health Service, Hospital, Dental and Other Contract Health Service Reports

**SUMMARY:** Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection activity was previously published in the Federal Register (61 FR 17903) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow 30 days for public comments to be submitted to the OMB. The IHS may not conduct or sponsor, and the respondent is not required to respond to any information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: Title: Indian Health Service Contract Health Service Reports. Type of Information Collection Request: A 1-year reinstatement with change of previously approved information collection 0917-0002, Indian Health Service contract Health Service Reports" Need and Use of Information Collection: These information collection forms are completed by IHS CHS Providers and used to certify that the health care services requested and authorized by the IHS have been performed by the CHS Provider(s), process payments for health care services performed by such providers; and serve as a legal document for health and medical care authorized by the IHS and rendered by providers under contract with the IHS. The burden estimate for this information collection activity follows:

Information collection activity	No. of respondents	Responses per re- spondent	Average burden per response (hours) 1
IHS-43-1A IHS-57-1A IHS-64-1A New form: IHS-843-1A Inpatient Discharge Summary 2	429 403 5,768 6,600 63,492	22 32 41	0.167 (10 mins). 0.418 (25 mins). 0.167 (10 mins). 0.05 (3 mins).

<sup>&</sup>lt;sup>1</sup> Provided in decimal unit values of an hour and in actual minutes.

**REQUEST FOR COMMENTS: Written** comments and suggestions from the public and affected agencies are invited on one or more of the following points: (a) Whether the information collection activity is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine the estimate; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office

of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS. To request more information on the proposed information collection activity or to obtain a copy of the data collection plan(s) and/or instrument(s), contact: Mr. Lance Hodahkwen, Sr., M.P.H., IHS Reports Clearance Officer, 12300 Twinbrook Plaza, Suite 450, Rockville, MD 20857; or call non-toll-free number (301) 443-0461; or send via facsimile to (301) 443-1522 or Internet (include your address) to: Lhodahkw@ihs.ssw.dhhs.gov.

**COMMENTS DUE DATE:** Comments regarding this information collection activity are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 28, 1996.

Michael H. Trujillo,

Assistant Surgeon General, Director.
[FR Doc. 96–23551 Filed 9–13–96; 8:45 am]
BILLING CODE 4160–16–M

## Office of Inspector General

**Program Exclusions: August 1996** 

**AGENCY:** Office of Inspector General, HHS.

**ACTION:** Notice of program exclusions.

During the month of August 1996, the **HHS Office of Inspector General** imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an

<sup>&</sup>lt;sup>2</sup>The inpatient discharge summary was overlooked as an information collection activity in prior approval requests and is added accordingly. In the **Federal Register** notice (61 FR 17903), the number of respondents and the average burden per response for the IDS were overstated. Both have been adjusted.

Federal F	Register / V	ol. 61, No. 180 / Monday	, September	16, 1996 / Notices	48711
excluded party even though no program payments will be made for items and		Subject, City, and State	Effective date	Subject, City, and State	Effective date
services provided by that exc		MUNSHEY, MUNIR, YPSI-		ALEXANDER, EARLE F.,	
party. The exclusions have n		LANTI, MI	09/11/96	BROOKLYN, NY	09/05/96
effect and also apply to all Ex		NURSES NOW AGENCY,	00/11/00	ALUL, MOHAMMAD, ST.	00/00/00
Branch procurement and nor		INC., EAST PATCHOGUE,		CHARLES, MO	09/11/96
procurement programs and a	ctivities.	NY	09/05/96	ANCIER, STEPHEN LEE,	
	F# C	PROSKUROVSKAYA,		UPPER MONTCLAIR, NJ	09/09/96
Subject, City, and State	Effective date	GALINA, BROOKLYN, NY	09/05/96	ANDERSON, MARY ANN,	
	date	RAVAL, KANU, JERSEY		MAPLEWOOD, MN	09/11/96
PROGRAM-RELATED CON-		CITY, NJ	09/05/96	ARTMAN, CARL, FARMING-	00/44/00
VICTIONS:		ROBINSON, SHIRLEY ANN,	00/45/00	TON, MO	09/11/96
ACQUAH, SABINA E., AB-		LITTLE ROCK, AR	09/15/96	BEN-AMOZ, DANIEL, CLIF-	09/05/96
ERDEEN, MD	09/10/96	ROSENBERG, MICHAEL GUTTMAN, LOS ANGE-		TON PARK, NJ BLOOM, BARRY IRVING,	09/05/96
AHDALLA, IZZELDIN,		LES, CA	09/10/96	NEW YORK, NY	09/05/96
WAUPUN, WI	09/11/96	ULLRICH, HARRY W.,	03/10/30	BROWN, JAMES JOSEPH,	00/00/00
ANDO, TEODORO A., WEB-	00/40/00	WHITE PLAINS, NY	09/05/96	ST. CHARLES, MO	09/11/96
STER, NY	09/10/96	VAINER, RAISA, BROOK-		BURKE, ALAN M, GENEVA,	
ANDO, AMYRELLIS L., WEBSTER, NY	09/10/96	LYN, NY	09/05/96	NY	09/05/96
ASAD, ALI, STATEN IS-	09/10/90	VOLPE, ANGELO, MEL-		CARLETON DENTAL	
LAND, NY	09/05/96	VILLE, NY	09/05/96	GROUP, P.C., CENTRAL	
ASIF, MUHAMMAD ANWAR,	00,00,00	YASIN, INC., COLUMBIA,		ISLIP, NY	09/05/96
KEW GARDENS, NY	09/05/96	MD	09/10/96	CHACE, HENRY V.,	
BAKER, TONYA, RIVER-		PATIENT ABUSE/NEGLECT		BAYSIDE, NY	09/05/96
DALE, GA	09/11/96	CONVICTIONS:		FINLEY, OLIVIA I., WASH-	00/40/00
BARKER, GORDON,		BEARD, PATSY JEAN,		INGTON, DC	09/10/96
BRIDGMAN, MI	09/11/96	JONESBORO, LA	09/15/96	GALINSKY, RONALD C., VOORHEES, NJ	09/09/96
BEGGS, KENNETH, PHILA-		BUTIKOFER, GORDON	00/10/00	GARDNER, ELMER A.,	09/09/90
DELPHIA, PA	09/10/96	RAY, MANTI, UT	09/10/96	BROOKESVILLE, MD	09/10/96
BOWMAN, JACQUELINE,	00/05/06	CARTER, SHARON, TUCK-	00/45/06	GILBERT, ROBERT DANIEL,	337.3733
YORKTOWN HGTS, NY BRYAN, TIANE, EIGHT	09/05/96	ER, AR DABNEY, ARTHUR JR.,	09/15/96	MONROE, LA	09/15/96
MILES, AL	09/12/96	PINE BLUFF, AR	09/15/96	GUZMAN, SILVIA, MESA,	
DEHON, MYRTIS LANG,	03/12/30	DAVIS, KATHRYN A., VAN-	09/13/90	AZ	09/10/96
KENNER, LA	09/15/96	COUVER, WA	09/10/96	HINZ, MARTIN C., DULUTH,	
DEW, DEBRA C.,		DELGADO, JAMES,		MN	09/11/96
TALLULAH, LA	09/15/96	CARRIZOZO, NM	09/15/96	HUTCHINGS, DANNY MI-	00/45/00
DEW, BILLY RAY SR.,		GRIFFITHS, EMMELIN,		CHAEL, VERNON, TX	09/15/96
TALLULAH, LA	09/15/96	MOUNT VERNON, NY	09/05/96	JONES, FLORENCE, PERU,	00/44/06
ETHERIDGE, JOHN CALEB,	00/45/00	HUTCHEN, NATALIE V.,		IN KITE, CHARLES H.,	09/11/96
PENSACOLA, FL	09/15/96	BUFFALO, NY	09/05/96	LOUDONVILLE, NY	09/05/96
FELDMAN, ALAN, MERRICK, NY	09/05/96	KLEDITZ, ERICH, SCAN-	00/44/00	LUPINACCI, ALAN, W.	03/03/30
FINKEL, RICHARD F., BOCA	09/03/90	DINAVIA, WI	09/11/96	PATERSON, NJ	09/09/96
RATON, FL	09/11/96	LADAGA, JOSEPH H.,	00/44/06	MARTIN, DANIEL BRIAN,	
GRISBA, MAY DORIS,	00/11/00	THREE RIVERS, MI MOLDEN, LONDA, MOSS	09/11/96	ARLINGTON, VA	09/10/96
HAZLELHURST, MS	09/15/96	POINT, MS	09/15/96	MATZ, RODNEY S.,	
HAMBERG, IVAN, ELKINS		ORTIZ, PETER J., ELMIRA,	03/13/30	WAYNE, NJ	09/09/96
PARK, PA	09/10/96	NY	09/05/96	MOZULAY, MARK JOSEPH,	
HUMPHREY, ROGER, SIC-		ROBERTS, JEFFREY L.,		ALEXANDRIA, VA	09/10/96
ILY ISLAND, LA	09/15/96	BUFFALO, NY	09/05/96	NOLAND, VICKIE LYNN,	00/44/00
HUSSAIN, YASIN M., CO-	00/40/00	SEYMOUR, JACQUELYN D.,		PITTSBORO, IN	09/11/96
LUMBIA, MD	09/10/96	PLAQUEMINE, LA	09/15/96	NOVOSAD, CHARLES L. JR., POJOAQUE, NM	09/15/96
IBRAHIM, GASIM, JERSEY CITY, NJ	09/11/96	SIEGEL, IRVING, BE-		PARKER, JONATHAN W.,	09/13/90
ISHERWOOD, JOAN,	09/11/96	THESDA, MD	09/10/96	FAIRLAWN, NJ	09/09/96
WHITE PLAINS, NY	09/05/96	THOMPSON, LESLIE C.,	00/44/00	POLHEMUS, JAY, ANDER-	00,00,00
KING, KENTRINA LANETTE,	00,00,00	DETROIT, MI	09/11/96	SON, IN	09/11/96
TEMPLE HILLS, MD	09/10/96	WILLIAMS, PATRICK	00/44/06	PUCHTA-BROWN, KRIS-	
KUKASH, ABIGAIL, RICH-		SHANE, INA, IL WILSON, SHIRLEY, NEW-	09/11/96	TINE M, MANCHESTER,	
MOND, VA	09/05/96	TON, MS	09/15/96	TN	09/12/96
KUKASH, MAJDI, RICH-		·	00/10/00	RUUD, NORMA ALMA,	
MOND, VA	09/09/96	CONVICTION FOR HEALTH CARE FRAUD:		ATWATER, MN	09/11/96
LEDOUX, JULIA, MAMOU,	00/15/05	BAPTISTE, CHERYL		SCHERMER, JOHN W., EN-	00/00/00
LA	09/15/96	DICKERSON, BATON		GLEWOOD, NJ	09/09/96
LOBACHEVSKAYA, RASHIL,	00/05/06	ROUGE, LA	09/15/96	SCHOOLER, CHRISTIAN, NEW YORK, NY	09/05/96
BROOKLYN, NY LONG, JANICE, THEO-	09/05/96	SUMMERS, JAVONDA,		SPARTALIS, MENICOS,	03/03/30
DORE AL	09/12/96	NEW ORLEANS, LA	09/15/96	BROOKLYN NY	09/05/96

CIA, YUMA, AZ .....

TORRES, VERONICA GAR-

LICENSE REVOCATION/SUS-

PENSION/SURRENDER:

DORE, AL .....

WOODMERE, NY .....

MALICK, MUHAMMAD A.,

MARABLE, DEBRA K., PEEKSKILL, NY ..... 09/12/96

09/05/96

09/05/96

09/10/96

BROOKLYN, NY .....

INVER GROVE, MN ......

GRAND RAPIDS, MN ......

STROEMER, JOHN R.,

STUBER, STEVEN F.,

09/05/96

09/11/96

09/11/96

Subject, City, and State	Effective date	Subject, City, and State	Effective date		
UNGAR-SARGON, JULIAN,		JUBERT, ANGELA K.,			
NEW YORK, NY	09/05/96	NASHVILLE, TN	09/12/96		
VANDER KOOI, PAUL, OR- ANGE, IA	09/11/96	KASHANI, MORTAZA, HILL- SIDE, IL	09/10/96		
VENANZI, ENZO J., BLACK- WOOD, NJ	09/09/96	KETTERER, CYNTHIA L., PHILADELPHIA, PA	09/10/96		
WESSER, DAVID ROBERT,	00,00,00	KRATT, THOMAS WILLIAM,	00,10,00		
ARDSLEY, NY	09/05/96	NACOGDOCHES, TX	05/29/96		
FEDERAL/STATE EXCLU-		LAYMAN, KEVIN WAYNE, ALMA, AR	09/15/96		
SION/SUSPENSION: CARLONI, EDMUND L.,		LINVILLE, MICHAEL R.,	03/13/30		
HARTSDALE, NY	09/11/96	SOMERVILLE, MA	09/11/96		
CENTRAL CARE, INC.,	00/00/00	MEISNER, JOHN T., BOGA- LUSA, LA	09/15/96		
CONGERS, NY FILIZ, GENCER, BROOK-	09/09/96	MELTON, TERRY L., OLD	09/13/90		
LYN, NY	09/09/96	HICKORY, TN	09/12/96		
GALLARDO, ANNETTE,		MILLER, KEVIN DWAYNE,	00/45/00		
CONGERS, NY	09/09/96	EUNICE, LA MIRRIONE, JOHN J.,	09/15/96		
GOMES, GERSON, FLUSH- ING, NY	09/09/96	WASHINGTON TWNSHP,			
JEAN-BAPTISTE, ROO-	00/00/00	NJ	09/09/96		
SEVELT, CHICAGO, IL	09/11/96	MOINI, KIAN, FOUNTAIN	00/40/00		
KLIMOVA, LUBOV T.,	00/00/06	VALLEY, CAODETTE, CAROLINE K.,	09/10/96		
BROOKLYN, NY RIVAS, LUIS, BRONX, NY	09/09/96 09/09/96	HOUSTON, TX	09/15/96		
OWNED/CONTROLLED BY	00,00,00	ONYEKAHA, EBERE N., MA-			
CONVICTED/EXCLUDED:		PLEWOOD, NJ	09/09/96		
AMERICAN MEDICAL		RESNANSKY, ALEXANDER, RICHFIELD SPRNG, NY	09/09/96		
SERVICES, INC., VOOR- HEES, NJ	09/10/96	REYNOLDS, BOB R., BA-	00/00/00		
DEW TRANSPORTATION,	09/10/90	KERSFIELD, CA	09/10/96		
TALLULAH, LA	09/15/96	SAUNDERS, RONALD W., SAN ANTONIO, TX	09/15/96		
MEDICINE SHOPPE, COLO-	00/40/00	SIGH, EDWARD R., FT.	09/15/96		
RADO SPRINGS, CO SAFETY MEDICAL TRANS-	09/10/96	STOCKTON, TX	09/15/96		
PORTATION, PENSA-		SIMON, MICHELLE R.,	00/40/00		
COLA, FL	09/15/96	THOUSAND OAKS, CA SLAVIN, TIMOTHY, FLORAL	09/10/96		
DEFAULT ON HEAL LOAN:		PARK, NY	09/09/96		
ANTHONY, STEVEN M., LAKE ELSINORE, CA	09/10/96	TAYLOR, ROGER A., SAN			
AVER, REVA B., PORT-	09/10/90	MATEO, CAVERBARO, DENNIS S.,	09/10/96		
LAND, OR	09/10/96	CHESTER, NJ	09/09/96		
BAKER, YVETTE KETAI, LITTLE ROCK, AR	00/45/06	WATSON, PERRY F.,			
BEAVER, BART D., EVER-	09/15/96	GRANVILLE, OH	09/11/96		
GREEN PARK, IL	09/11/96	WILBERT, LEONARD BRIAN, VINITA TERRACE,			
BONO, JOHN E., SAN	00/40/00	MO	9/11/96		
JOSE, CA CARY, HUNSDON R., AR-	09/10/96				
LINGTON, TX	09/15/96	Dated: September 9, 1996.			
CLUNES, LINDSAY C.,		William M. Libercci,	44		
CORVALLIS, OR CONTI, ANTHONY N., MED-	09/10/96	Director, Health Care Administra Sanctions, Office of Enforcement			
FORD, NY	09/09/96	Compliance.	ana		
DIBENEDETTO, MAURO V.,		[FR Doc. 96–23568 Filed 9–13–9	6; 8:45 am]		
MASSAPEQUA, NY	09/09/96	BILLING CODE 4150-04-P	•		
DRABINSKY, GERALD S., LOS ANGELES, CA	09/10/96				
EARLY, GARY M.,	03/10/30	National Institutes of Health			
KIRKSVILLE, MO	09/11/96	National institutes of Health	1		
FISHKIN, WILLIAM H., SAN FRANCISCO, CA	09/10/96	Government-Owned Inventions;			
GARCIA, ROBERT WILLIAM, ODESSA, TX	09/15/96	Availability for Licensing  AGENCY: National Institutes of Health,			
GERVASI, CININA M., LONG BEACH, NY	09/09/96	HHS.			
HEALEY, CHRISTINE J.,	03/03/30	ACTION: Notice.			
WINTHROP, MA	09/11/96	The inventions listed below			
HITCHCOCK, PHILIP R.,	00/40/06	The inventions listed below are owned by agencies of the U.S.			
DUNSMUIR, CA JAFAR, WIDAD J., WHITE-	09/10/96	Government and are available for			
HALL, PA	09/10/96	licensing in the U.S. in accor			
		-			

35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

ADDRESSES: Licensing information and

addresses: Licensing information and copies of the U.S. patent applications and issued patents listed below may be obtained by contacting Ken Hemby at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7735 ext 265; fax: 301/402–0220). A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Expression of Early Lung Cancer Detection Market P31 in Neoplastic and Non-Neoplastic Respiratory Epithelium

JL Mulshine (NCI) Filed 02 Oct 95 Serial No. 08/538,711

Lung cancer is the most frequent cause of cancer death in both males and females in the United States. Metastatic lung cancer is almost uniformly fatal. Methods for earlier detection of lung carcinoma may help increase survival rates by allowing earlier treatment. Recently, there have been efforts to detect antigens associated with lung carcinoma in the sputum of patients. The basis of this approach is the identification of early, potentially preneoplastic changes in cells shed from bronchial epithielium. This invention identifies P31 as a candidate for a lung carcinoma associated antigen which can be detected in sputum using immunological methods. This invention describes production and use of antibodies specific for P31 antigen which are highly correlated with patients having increased age and prolonged smoking history, and is selective for neoplastic tissue or tissue proximally associated with neoplasms. This invention further defines a method by which other candiate early lung cancer detection markers can be evaluated. Issuance of a patent on this invention is currently pending. (portfolio: Cancer—Diagnostics, in vitro, MAb based; Cancer—Research Reagents, MAb based)

Colon Mucosa Gene Having Down-Regulated Expression in Colon Adenomas and Adenocarcinomas

CW Schweinfest, TS Papas (NCI) Filed 17 Apr 95 Serial No. 08/424,567 (FWC of 08/ 026,045)