side effects claims, unless the claim is true and substantiated by scientific evidence.

Part II prohibits respondents from making any representation for any food, drug, or dietary supplement that contains ephedrine alkaloids that consumers can appropriately take such product in an amount that exceeds the level established by any regulation of the Food and Drug Administration (''FDA'') for ephedrine alkaloids or any other ingredient in the product.

Part III requires the following clear and prominent disclosure in all future advertising and labeling of, and all consumer communications concerning, any ephedrine-alkaloid-containing product sold by respondents:

Warning: This product contains ephedrine which can have dangerous effects on the central nervous system and heart and could result in serious injury. Risk of injury increases with dose.

Under Part III, if the product is subject to an FDA rule or regulation that requires a labeling warning, that warning is required in labeling in lieu of the warning set forth above.

Part IV prohibits respondents from assisting others, including by selling product to them, when respondents have reason to believe that they are deceptively promoting respondents' ephedrine-containing products.

Part V prohibits misrepresentations about endorsements and testimonials.

Part VI prohibits respondents from directing to individuals under the age of twenty-one advertising and promotional activities for Ecstasy or any other ephedrine product marketed as an alternative to an illegal drug or for its euphoric, psychotropic, or sexual effects. Part VI includes examples of prohibited activity, including advertisements and promotions to audiences half or more under twenty-one.

Part VII requires the respondents to conduct and submit annual analyses of the levels of ephedrine alkaloids in any ephedrine-containing product that they sell for the next five (5) years.

Part VIII provides that nothing in the order permits the respondents to market any product (1) in a state where its sale has been banned; (2) in a manner that is inconsistent with state restrictions on its sale; or (3) in a way that is inconsistent with any applicable FDA rule or regulation.

Parts IX and X provide safe harbors for claims approved pursuant to FDA's regulation of the labeling for drugs and foods, respectively.

Part XI requires respondents to send a letter (Attachment A to the order) to anyone who provides the public with information about any of respondents' ephedrine-containing products. The letter advises the recipient that the disclosure required by Part III of the order must be made in all communications with consumers concerning any of respondents' ephedrine-containing products and that the only permissible statement about the dose of any such product is the information on the label. Part XII sets forth the record keeping and surveillance requirements with respect to Part XI.

Part XIII requires respondents to send a letter (Attachment B to the order) to distributors and resellers, including any person who purchases more than 100 units of any of respondents' ephedrine-containing products in any there (3) month period. The letter describes the Commission's action in this case and advises recipients to discontinue use of any promotional materials that do not comply with the order. Part XIV set forth the record keeping and surveillance requirements with respect to Part XIII.

The remaining parts of the order contain standard provisions pertaining to record keeping, compliance, sunsetting of the order, and similar matters.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Reporting Requirements for the National Health Service Corps (NHSC) Non-Grant Sites—New—The National Health Service Corps (NHSC) is a component of the Bureau of Primary Health Care, Health Resources and Services Administration, Department of Health and Human Services. The mission of the NHSC is to assist in the development, recruitment, and retention of community-responsive, culturally competent, primary care providers to serve people in health professional shortage areas. The mission is implemented through assignment of personnel to 365 BPHC grant-supported health care sites and 312 sites receiving no grant support.

The NHSC is required to collect specific data from the sites to which NHSC providers are assigned. For grant-supported sites, this is accomplished through the Uniform Data System (UDS)(OMB No. 0915–0193). The UDS data are utilized to comply with congressionally mandated actions such as billing sites for the reimbursement of the cost of NHSC assignees and preparing reports for Congress. The UDS data are also utilized for evaluating the overall effectiveness of the NHSC to include appropriateness of NHSC assignee placements and expenditure of funds.

This request is to collect a subset of the UDS data from the non-grant supported sites in order to facilitate full compliance with the congressionally mandated billing and reporting requirements.

For this purpose a modified reporting tool with less burden has been developed for the non-grant supported sites which will collect information on services provided, populations served, staffing and utilization, finances, and managed care enrollment.

The following burden table was developed based on experience with

grant supported sites in completing the UDS:

Type of instrument	No. Of Respondents	Responses per Respondent	Hours per Response	Total Hour Burden
Modified UDS	312	1	5.6	1,747

The annual burden estimates shown above for the non-grant supported sites to complete the required six Tables will be refined through field testing at nine randomly selected sites.

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD, 20857. Written comments should be received within 60 days of this Notice.

Dated: July 25, 1997.

Jane Harrison,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 97–20453 Filed 8–1–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Proposed Collection; IHS Contract Health Service Report

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, to provide a 60-day advance opportunity for public comment on proposed data collection projects, the Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection project to be submitted to the Office of Management and Budget (OMB) for review.

Proposed Collection

Title: 09–17–0002, ''IHS Contract Health Service Report.''

Type of Information Collection Request: 3-year reinstatement, with change, of previously approved information collection, 09–17–0002, ''IHS Contract Health Service Report'' which expire 09/30/97.

Form Number: IHS–843–1A, ''Purchase-Delivery Order for Health Services.''

Needs and Use of Information Collection: The Contract Health Service health care providers complete form IHS–843–1A to certify that they have performed the health services authorized by the IHS. The information is used to manage, administer, and plan for the provision of health services to eligible American Indian patients, process payments to providers, obtain program data, provide program statistics, and, serves as a legal document for health care services rendered.

Affected Public: Businesses or other for-profit, Individuals, not-for-profit institutions and State, local or Tribal Government.

Type of Respondents: Health care providers.

Table 1 below provides: Type(s) of Data Collection Instruments, Estimated Number of Respondents, Number of Responses per Respondent, Average Burden Hour per Response, and Total Annual Burden Hour.

TABLE 1

Data collection instrument	Estimated number of respondents	Responses per respondent	Annual number of responses	Average Burden hr per response*	Total annual burden hours
IHS–843–1A	9,115	43	393,416	0.05 (3 mins)	19,670
IDS**	21,797	1	21,797	0.05 (3 mins)	3,175

* For ease of understanding, burden hours are also provided in actual minutes.
** Inpatient Discharge Summary (IDS).

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Request for Comments

Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Send Comments and Requests for Further Information

Send your written comments, requests for more information on the proposed project, or requests to obtain a copy of the data collection instrument and instructions to: Mr. Lance Hodahkwen, Sr., M.P.H., IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852, 1601, call non-toll free (301) 443–0461, fax (301) 443–1522, or send your E-mail requests, comments, and return address to: lhodahkw@.ihs.gov.

Comment Due Date

Your comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publications.