

physician services after the transfer of ownership to Renal Advantage. Similarly, the Consent Agreement requires DaVita to obtain the consent of all lessors necessary to assign the leases for the real property associated with the divested clinics to Renal Advantage. These provisions ensure that Renal Advantage will have the assets necessary to operate the divested clinics in a competitive manner.

The Consent Agreement contains several additional provisions designed to ensure that the divestitures are successful. First, the Consent Agreement provides Renal Advantage with the opportunity to interview and hire employees affiliated with the divested clinics and prevents DaVita from offering these employees incentives to decline Renal Advantage's offer of employment. This will ensure that Renal Advantage has access to patient care and supervisory staff who are familiar with the clinics' patients and the local physicians. Second, the Consent Agreement prevents DaVita from contracting with the medical directors (or their practice groups) affiliated with the divested clinics for three years. This provides Renal Advantage with sufficient time to build goodwill and a working relationship with its medical directors before DaVita can attempt to capitalize on its prior relationships in soliciting their services. Third, to ensure continuity of patient care and records as Renal Advantage implements its quality care, billing, and supply systems, the Consent Agreement allows DaVita to provide transition services for a period of 12 months. Firewalls and confidentiality agreements have been established to ensure that competitively sensitive information is not exchanged. Fourth, the Consent Agreement requires DaVita to provide Renal Advantage with a license to use DaVita's policies and procedures, as well as the option to obtain DaVita's medical protocols, which will further enhance Renal Advantage's ability to provide continuity of care to patients. Finally, the Consent Agreement requires DaVita to provide prior notice to the Commission of its planned acquisitions of dialysis clinics located in the 35 markets addressed by the Consent Agreement. This provision ensures that subsequent acquisitions do not adversely impact competition in the markets at issue and undermine the remedial goals of the proposed order.

The Commission is satisfied that Renal Advantage is a qualified acquirer of the divested assets. Renal Advantage is a newly-formed company whose management has extensive experience

operating, acquiring, and developing outpatient dialysis clinics. The company has received a substantial equity investment from Welsh, Carson, Anderson, and Stowe, which is the largest healthcare-focused private equity firm in the United States.

The Commission has appointed Mitch Nielson and John Strack of FocalPoint Medical Consulting Group ("FocalPoint") as Monitors to oversee the transition service agreements, and the implementation of, and compliance with, the Consent Agreement. Messrs. Nielson and Strack are the principles of FocalPoint, which provides consulting services to the healthcare industry.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or the Order to Maintain Assets, or to modify their terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 05-20312 Filed 10-7-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-06-05CW]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-371-5983 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

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. Written comments should be received within 60 days of this notice.

Proposed Project

Online Surveys to Measure Awareness of Chronic Fatigue Syndrome Public Awareness Campaign (OMB Control No. 0920-05CW)—New—National Center for Health Marketing (NCHM), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Chronic fatigue syndrome (CFS) is a serious illness that affects many Americans. With as many as 900,000 cases, many of which are misdiagnosed or left undiagnosed, the need for a CFS public education and awareness campaign is crucial.

With an estimated \$9.1 billion lost annually in U.S. productivity due to CFS, the economic impact is a substantial reason for Americans to take notice. More importantly, the diminished quality of life for many patients suffering from CFS is especially hard to manage. The lack of quality information regarding CFS makes it all the more difficult for those affected by CFS to receive the support and treatment needed to manage this illness.

Research shows that 80 to 90 percent of patients have not been clinically diagnosed and are not receiving proper medical care. Lack of awareness and information among health care providers about CFS as a serious and treatable illness has created significant barriers to diagnosing and treating those who suffer from CFS.

Congress recognized the need to change this scenario, as reported in the Committee Reports for the Senate Appropriations Committee (Senate Report 108-345—To accompany S. 2810 Sept. 15, 2004) when the committee stated:

Further, the Committee encourages CDC to better inform the public about this condition, its severity and magnitude and to use heightened awareness to create a registry of CFS patients to aid research in this field.

During the next two years, CDC, in partnership with the Chronic Fatigue and Immune Dysfunction Syndrome (CFIDS) Association of America, will build the case that chronic fatigue syndrome is real, serious and should be diagnosed quickly to ensure the best possible health outcomes.

To do so, a public education and awareness campaign will be launched to bring about changes in beliefs and social norms among target audiences (consumers: women aged 40–60, healthcare practitioners: nurse practitioners and physician assistants)

that CFS is a diagnosable and treatable physical illness.

Although considerable research will be done to ensure that campaign themes, messages, and materials are effective, there is no way to test the impact of the campaign on the target audience other than to conduct baseline

and follow-up surveys. These surveys will measure not only the level of awareness created by the campaign, but will measure change in key knowledge, attitudes and beliefs about CFS among the target audiences. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondents	Instrument	Number of respondents	Number of responses per respondent	Response burden per respondent (in hours)	Total annual burden (in hours)
Consumers (Women, 40–60 years of age)	Pre-program survey	400	1	10/60	67
Consumers (Women, 40–60 years of age)	Post-program survey	400	1	10/60	67
Physician Assistants	Pre-program survey	200	1	10/60	33
Physician Assistants	Post-program survey	200	1	10/60	33
Nurse Practitioners	Pre-program survey	200	1	10/60	33
Nurse Practitioners	Post-program survey	200	1	10/60	33
Total					266

Dated: October 4, 2005.

Betsey Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–20323 Filed 10–7–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0526]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 7, 2005 (70 FR 33177), the agency announced that the proposed information collection had been submitted to OMB for review and

clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0389. The approval expires on August 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 3, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20305 Filed 10–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0083]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, and Forms FDA 356h and 2567

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “General Licensing Provisions: Biologics License Application, Changes

to an Approved Application, Labeling, Revocation and Suspension, and Forms FDA 356h and 2567” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 21, 2005 (70 FR 42068), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0338. The approval expires on September 30, 2008. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 3, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20306 Filed 10–7–05; 8:45 am]

BILLING CODE 4160–01–S