continues to be identifying patient outcomes that are sensitive to nursing care.

The primary areas proposed for future research focusing on the impact of nurse staffing on the quality of care in hospitals include:

- What is the relationship between the organization and delivery of nursing care and patient outcomes? What are the key organizational variables that influence staff performance and outcomes?
- What are the unique skills and the mix of registered nurses and other nursing and ancillary staff that impact on outcomes? This includes understanding what work needs to be done for patients to impact patient outcomes and who are the best people to do it.
- What specific organizational variables and delivery of care variables are related to specific patient outcomes? Specific questions within this category include: What is the relationship between nursing skill mix and achievement of outcomes such as appropriate self-care? What are the relative contributions of nurse, patient, other clinicians (e.g., M.D.), and organizational factors to specific patient outcomes?
- What is the impact of computer technology on patient outcomes? Included in this area are questions about the use of decision support that may extend off-site clinical expertise to hospital nursing staff. Also included are questions about the data elements about nursing and nurses that should be routinely collected.
- What is costworthy in an era when limited resources are available for hospital care? Although a nursing intervention may work for a clinical problem and even be more effective than other interventions, there may be other diseases or clinical problems that affect more people and also have cost-effective interventions.

At the AAN Conference, the following patient outcomes were identified for further refinement by research teams: achievement of appropriate self-care, demonstration of health-promoting behaviors, health-related quality of life, perception of being well cared for (broadened beyond patient satisfaction), symptom management, and adverse outcomes. Other outcomes of interest relate to the patient's family and community.

In line with the recommendations of the IOM Report the specific focus of this proposed research agenda is the relationship between nurse staffing and quality of care in hospitals. However, comments and suggestions about research pertaining to nurse staffing and quality in other types of delivery settings are welcome by AHCPR, NINR, and DN (HRSA).

Dated: November 6, 1996.

Clifton R. Gaus,

Administrator.

[FR Doc. 96–28997 Filed 11–12–96; 8:45 am]

BILLING CODE 4160–90–M

Food and Drug Administration

[Docket No. 88P–0439]

Medical Devices; Reclassification of Suction Lipoplasty System for Aesthetic Body Contouring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of panel recommendation.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment the recommendation of the General and Plastic Surgery Devices Panel (the Panel) to reclassify the suction lipoplasty system for aesthetic body contouring from class III to class II. The Panel made this recommendation after reviewing the reclassification petition submitted by the American Society for Aesthetic Plastic Surgery (ASAPS) and other publicly available information. FDA is also issuing for public comment its tentative findings on the Panel's recommendation. After considering any public comments on the Panel's recommendation and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in the form of a letter to the petitioner. FDA's decision on the reclassification petition will be announced in the Federal Register.

DATES: Written comments by February 11, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Stephen P. Rhodes, Center for Devices and Radiological Health (HFA–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION: On December 28, 1988, ASAPS submitted a petition under section 513(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e)), requesting that the suction lipoplasty system intended for surgical use in aesthetic body contouring, be reclassified from class III into class II. The major components of this system, the cannula (a manual surgical instrument for general use (21 CFR 878.4800)), and the suction pump (powered suction pump (21 CFR 878.4780)) when intended for certain uses other than suction lipoplasty procedures are classified in class I and class II, respectively. However, when these devices, individually labeled or combined into a system, are intended for use in aesthetic body contouring, they are automatically classified into class III under section 513(f)(1) of the act.

Section 513(f)(2) of the act provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the agency to reclassify the device into class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the suction lipectomy system for use in aesthetic body contouring, it is necessary that the proposed new class has sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 310–394), (as amended by the Medical Device amendments of 1976 (the amendments) (Pub. L. 94–295), class II devices were defined as those devices for which there is insufficient information to show that general controls alone will ensure safety and effectiveness, but there is sufficient information to establish that performance standards would provide a reasonable assurance of safety and effectiveness of the device. In the time that has passed since the submission of the petition and the Panel meeting, the definition of class II devices has been amended by the Safe Medical Devices Act of 1990 (the SMDA). Under the SMDA, class II devices are those devices for which there is insufficient information to show that general controls alone will ensure safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance, including the issuance of a performance standard, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the agency deems necessary (section 513(a)(B) of the act).

It is the agency's position that is not necessary to obtain a new reclassification recommendation from a

Panel which had recommended reclassification into class II prior to the SMDA. If a Panel recommended that a device be reclassified from class III to class II under the 1976 definition of class II, which included only performance standards as a class II control, clearly the Panel's recommendation for class II status would not change if controls in addition to performance standards could be added.

I. Background

In 1983 three firms submitted four premarket notifications to FDA under section 510(k) of the act (21 U.S.C. 360(k)) advising the agency of their intentions to place into commercial distribution either the suction cannula or the powered suction pump for use in suction lipoplasty for aesthetic body contouring. FDA determined that neither the suction cannula nor the powered suction pump for aesthetic body contouring was substantially equivalent to any preamendments device, nor was either device substantially equivalent to any postamendments device that had been classified into class I or class II for use in suction lipectomy for aesthetic body contouring. Accordingly, both devices were classified into class III under section 513(f)(1) of the act, and neither device could be placed in commercial distribution for use in suction lipoplasty for aesthetic body contouring unless it was reclassified under section 513(f)(2), or subject to an approved premarket approval application under section 515 of the act (21 U.S.C. 360e).

Subsequently, ASAPS initiated a clinical trial to identify the risks associated with suction lipoplasty procedures and to determine the relationship of the risks to characteristics of suction lipoplasty devices and thereby develop measures to minimize or control the risks (Ref. 1). After completing the clinical trial, ASAPS petitioned FDA to reclassify suction lipoplasty systems for use in aesthetic body contouring from class III into class II (Ref. 1). Consistent with the act and applicable regulations, the agency referred the petition to the Panel for its recommendation on the requested change in classification.

II. Recommendation of the Panel

The Panel met on January 26, 1989, in a public meeting and on March 10, 1989, via a telephone conference to discuss the suction lipoplasty systems intended for use in aesthetic body contouring. During the January 6, 1989, meeting, the Panel determined that additional data and information were indicated and that another panel meeting would be necessary to allow the Panel to address specific issues concerning the reclassification of the suction lipoplasty systems (Ref. 2). The Panel noted that the suction lipoplasty system is indicated for aesthetic body contouring (Ref. 2, p. 52) and is not intended to be a substitute for a weight reduction regimen. On March 10, 1989, after considering the device components and accompanying surgical risks as addressed in the petition and literature, the Panel recommended that the suction lipoplasty systems intended for aesthetic body contouring be reclassified from class III into class II (Ref. 3, p. 95). The Panel also recommended that FDA assign a high priority for the development of a performance standard for the generic type device.

III. Device Description

The suction lipoplasty system consists of a powered suction pump (containing a microbial filter on the exhaust and a microbial in-line filter in the connecting tubing between the collection bottle and the safety trap), collection bottle, cannula, and connecting tube. The microbial filters, tubing, collection bottle, and cannula must be sterile and capable of being changed between patients. The powered suction pump has a motor with a minimum of 1/3 horsepower, a variable vacuum range from 0 to 29.9 inches of mercury, vacuum control valves to regulate the vacuum with accompanying vacuum gauges, single or double rotary vane (oil or oil-less), single or double diaphragm, single or double piston, and a safety trap (Ref. 4). The pump meets the voluntary Underwriters Laboratories (UL) UL–455 Standards for Medical and Dental Equipment (Ref. 5). The collection bottle is calibrated to permit precise continual monitoring of the amount of material being removed from the patient. The cannulas are composed of biocompatible material such as plastic or surgical grade stainless steel with various dimensions and configurations determined by the particular application or surgical site and preference of the individual surgeon (Refs. 4, 6, and 7). The connecting tubing has an internal diameter appropriate to the size of the cannula handle, generally 7.5 to 12.5 millimeters. The tubing is able to withstand the amount of negative pressure created by the pump without collapsing.

The device is used in the clinical field of plastic surgery for the purpose of aesthetic body contouring.

IV. Summary of Reasons for the Recommendation

After reviewing the data and information contained in the petition and provided by FDA, and after consideration of the open discussions during the Panel meetings and the Panel members' personal knowledge of and clinical experience with the device system, the Panel gave the following reasons in support of its recommendation to reclassify the generic type suction lipoplasty system for use in aesthetic body contouring from class III into class II:

(1) General controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

(2) There is sufficient publicly available information to establish a performance standard to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

(3) There is sufficient publicly available information to demonstrate that the risks to health and the performance parameters of the device have been characterized and that the relationship of these risks and performance parameters have been evaluated (Refs. 8, 11, and 12).

(4) Sufficient voluntary standards exist to reasonably assure the design and performance of the device system (Refs. 5, 13, 14, 15, 16, and 26).

The Panel believed that current and any subsequent manufacturer of the suction lipoplasty system can comply with these voluntary standards and a performance standard; that FDA can assure the safety and effectiveness of device systems made by new manufacturers through premarket notification procedures under section 510(k) of the act; and that a regulatory level of class III is unnecessary to provide a reasonable assurance of safety and effectiveness.

V. Risks to Health

The Panel determined that the foreseeable risks to health associated with the use of the suction lipoplasty system fall into two categories: (1) Those related to the device system that include the potential of infection of a subsequent patient resulting from the backflow of contaminated material trapped by the in-line filter during the preceding procedure, and (2) those related to the suction procedure that include tissue trauma (i.e., pain, nerve and blood vessel damage, hypesthesia, and hemorrhage). The degree of tissue trauma is believed to be related to the amount of vacuum applied and the type

of cannula used during the procedure (Refs. 10, 17, 18, and 19).

After reviewing the Panel meeting transcripts, the petition, and the relevant literature, FDA identified other potential risks which include airborne bacterial or viral contamination of other patients and hospital personnel resulting from inefficient or overused in-line filters, patient bio-incompatibility to materials, and infection resulting from improper sterilization or practitioner handling.

Several of the procedure-related risks reported in the literature (fat embolism, venous thrombosis, hematoma/seroma, pain, infection, necrosis/skin slough, edema, hypovolemia/hypotension, and potential death (Refs. 8, 11, 20, 21, 22, and 23)) were not observed in the petitioner's clinical studies and other procedure-related risks were reduced when the surgical procedure was performed by adequately trained surgeons on properly selected patients.

In general, the best candidates for liposuction are healthy individuals who have concentrated areas of fat and firm, elastic skin. Age is usually a criterion for a healthy patient. However, after age 55, some patients lose skin elasticity and will not achieve the same good results as a younger patient.

Liposuction is not recommended for patients with heart or lung diseases, poor blood circulation, diabetes, or those who have had recent surgery near the area of fat to be suctioned. Patients who are obese with diffuse areas of fat are not considered ideal candidates because of a greater risk of complications. However, in some cases, a series of carefully controlled procedures may be an effective adjunct to a weight-loss program.

(Ref. 24)

VI. Benefits

Suction lipoplasty systems provide benefits to patients by effectively performing aesthetic body contouring. The benefits of these devices are probably best characterized in terms of patient satisfaction. The ASAPS study reported 56 percent of patients being very satisfied, 34 percent satisfied, and 6 percent not satisfied. Two other large studies reported overall satisfaction rates of 88 and 76 percent, respectively (Refs. 8 and 9). Both studies found dissatisfaction rates highest in patients who had undergone liposuction of the buttocks. From the physicians' survey, review of the long-term results reveal that less than half of the respondents reported totally permanent results. Twenty nine percent reported fat ''regrowth'' as minimal and 62 percent were satisfied with the results.

VII. Summary Data Upon Which the Panel Recommendation is Based

During its review and discussion of the petition, the Panel paid close attention to the potential risks and benefits to health associated with the use of the suction lipoplasty system and concluded that the data and information contained in the petition and presented by FDA demonstrated that the risks to health associated with this system could be adequately controlled (Ref. 1). The Panel relied on the following information in recommending that the suction lipoplasty system for aesthetic body contouring be class II devices.

A 1988 ASAPS multicenter study (Ref. 1) provided some perspective of the above mentioned risks and complications. The study, using 2 different suction pumps and connective tubing and 8 different cannulas, reported that of the 113 patients in whom 189 procedures had been performed, where the amount of fluid aspirated ranged from 15 to 4,700 cubic centimeters per patient, there were no complications, undesired sequelae or health problems directly related to the device system used to perform liposuctions (Ref. 1, p. 24). The study also noted no mortality or episodes of shock, although 1 patient developed subcutaneous emphysema of the neck that was determined to be anesthesia related and 39 patients required postoperative transfusions. Other reported complication rates were hypesthesia, 46.6 percent; pain, 18.6 percent; change in pigmentation, 10.6 percent; and scarring (thickening of the skin) during the immediate postoperative period, 9.9 percent. Additional complications which occurred in less than 5 percent of patients include asymmetry, waviness, insufficient fat removal, hematoma, excessive fat removal, and edema. Most of these complications improved or resolved with time resulting in an overall complication rate of 4.1 percent. Many of the items listed as complications in the study would be classified as undesirable sequela by other authors (Ref. 1, p. 24).

A 1987 American Society of Plastic and Rescontructive Surgery (ASPRS) task force studied the safety of liposuction. Eleven deaths and nine nonfatal serious complications over a 5-year period (an estimated 100,000 cases) were documented (Ref. 12).

Two other major studies on liposuction devices have been completed since the January 26, 1989, Panel recommendation. In 1989, a national survey of plastic surgeons was conducted. The findings of this survey identified a liposuction complication rate of 0.1 percent with 2 deaths among the 75,591 liposuction procedures analyzed in the survey. One death was caused by fat embolism and the other death by pulmonary thromboembolism. Twenty-five cases of deep venous thrombosis, 10 transfusion complications, 9 cases of pulmonary thromboembolism, 5 cases of major skin loss, 1 stroke, and 1 nonlethal fat embolus were reported (Ref. 11).

In 1990, the Fornebu Clinic in Norway conducted a study involving 3,511 liposuctions in 2,009 patients. It reported excessive bleeding in eight patients and anesthesia related complications in nine patients; however, no deaths, thromboembolic events, fat emboli or cardiovascular complications were reported (Ref. 8). Infection, an issue of particular concern to the Panel and to FDA, occurred in only 1 of the 2,009 patients. The low incidence of infection associated with liposuction devices is confirmed and supported by several other reports in which the infection rate was less than 1 percent (Refs. 7, 8, 10, and 25).

VIII. Panel Recommendation

The Panel concluded that the incidence of infections and other complications associated with liposuction using the suction lipoplasty system for aesthetic body contouring can be controlled by proper patient selection, utilization of the proper surgical technique, and restricting the use of the device to trained and experienced practitioners.

Focusing on other potential problems and performance aspects of the device system, the Panel considered the issues of electrical malfunctions; bacterial, viral, or oil contamination of the operating room; bioincompatibility of materials; reflux of possible contaminated aspirated material; and product labeling.

Regarding potential electrical malfunctioning of the components and properties of the device, the Panel believed that the UL–544 Standard for Medical and Dental Equipment (Ref. 2) can provide the necessary provisions to control the potential electrical hazards associated with the use of the suction pump. Likewise, the Panel believed that the American Society for Testing Materials (ASTM) F 960–86 Standard Specification for Medical and Surgical Suction and Drainage Systems can control the potential risk of leakage, risk of filtration, and implosion of the contaminants into the operating room by emissions from the exhaust port of the pump. Proper sterilization of the cannula and tubing can control the risk

of infection as indicated by the low rate of infection reported in the literature (Ref. 1, p. 29). The risk of oil vapor leakage can be reduced by properly maintaining the pump in oil based aspirators (Refs. 1 and 4). The Panel noted that there are no reports of viral transmissions to operating room personnel from aerosolization of aspirate (Ref. 4).

A major concern to the Panel was the reflux of possibly contaminated aspirated material from the collection bottle into the sterile surgical field. They concluded that filters and/or valves can minimize the potential risk of bacterial contamination of the cannula, surgical field, and operating room air.

The Panel believed the biocompatibility of materials used to manufacture the cannula can be assessed by voluntary standards established by ASTM (Ref. 13), United States Pharmacopeia (USP) (Ref. 14), and by methods described in Tripartite Biocompatibility Guidance for Medical Devices (Ref. 26), and that these test methods will provide reasonable assurance that the materials used to manufacture the device system, as well as any residues remaining on the devices after manufacturing, are not toxic and that the system is biocompatible. The Panel also believed that when the device is manufactured of materials that meet the specifications of existing voluntary standards, a biocompatible cannula can be produced thereby providing reasonable assurance of safety and effectiveness with respect to biocompatibility.

The Panel believed that device labeling should reflect the nature of the device as it relates to the intended use and should include appropriate directions for use, warnings, and precautions, based upon current scientific knowledge. The Panel further believed that the labeling should be accessible to physicians and patients.

In summary, the Panel believed that, based on publicly available valid scientific evidence, class II controls can provide reasonable assurance that the suction lipoplasty system is safe and effective for use in aesthetic body contouring. The Panel specified that the device conform to the provisions similar to those in the Tripartite Biocompatibility Guidance for Medical Devices, the above voluntary standards established by UL, ASTM, the Canadian Standards Association (CSA), the International Organization for Standardization (ISO), and USP, and specific labeling which identifies the appropriate patient selection criteria and surgeon training. The panel also recommended the issuance of a performance standard on a high priority basis.

IX. FDA's Tentative Findings

FDA believes that the data provided by the petitioners and others constitute valid scientific evidence demonstrating that the regulatory controls of class II in combination with class I are sufficient to provide reasonable assurance of the safety and effectiveness of the generic type lipoplasty system as identified in section III. of this document. FDA tentatively agrees with the recommendation of the Panel that the suction lipoplasty system for aesthetic body contouring and substantially equivalent devices of this generic type should be reclassified from class III into class II. The agency has identified the special controls as the four following voluntary standards: International Organization for Standardization (ISO) 10079–1, Medical Suction Equipment, Part 1, Electrically Powered suction Equipment—Safety Requirements, 1993 (Ref. 15); Canadian Standards Association (CSA), Standard Z168.11–94, Vacuum Devices Used for Suction and Drainage, 1994 (Ref. 16); Clinical Practice Guidelines, Plastic and Maxillofacial Surgery, American Society of Plastic and Reconstructive Surgeons, Chapter L: Localized Adiposity, September 1993 (Ref. 27); International Standard ISO–10993 Biological Evaluation of Medical Devices Part I Evaluation and Testing, 1995 (Ref. 28); and the inclusion of the following labeling statements to provide reasonable assurance of the safety and effectiveness of the suction lipoplasty system:

(1) This device is designed to contour the body by removing localized deposits of excess fat through small incisions.

(2) Use of this device is limited to those physicians who, by means of residency training or sanctioned continuing medical education, have demonstrated proficiency in suction lipoplasty.

(3) This device will not, in and of itself, produce significant weight reduction.

(4) This device should be used with extreme caution in patients with chronic medical conditions such as diabetes, heart or lung disease, circulatory diseases, or obesity.

(5) Results of this procedure will vary depending upon patient age, surgical site, and experience of the surgeon.

(6) Results of this procedure may or may not be permanent.

(7) The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.

(8) Loss of blood and fluid is predictable based on suction volume. Capability of providing adequate, timely replacement of these components is essential for patient safety.

(9) All reusable components of the device must be sterilized between patients and all disposable components replaced.

FDA does not believe that the performance standard recommended by the Panel is necessary because the voluntary standards listed above will provide a reasonable assurance of safety and effectiveness for the suction lipectomy system.

Consistent with the purpose of the act, class II controls as identified above and as defined by section 513(a)(1)(B) of the act are sufficient to provide reasonable assurance of the safety and effectiveness of the suction lipoplasty system.

X. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XI. Analysis of Impacts

FDA has examined the impacts of this proposed action under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed action is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed action is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of devices relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act, and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that this proposed action would not have a significant economic impact on

a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

XII. References

The following references have been placed on display in the Documents Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Reclassification Petition for the Suction Lipectomy Systems for Aesthetic Body Contouring, submitted by American Society for Aesthetic Surgery, December 28, 1989.

2. Transcript of the General and Plastic Surgery Devices Panel Meeting, January 26, 1989.

3. Transcript of the General and Plastic Surgery Devices Panel Meeting, March 10, 1989.

4. Pitman, G. H., ''Instrumentation,'' *Liposuction and Aesthetic Surgery*, Quality Medical Publishing Inc., St. Louis, MO, Part I, 2:31–36.

5. Underwriters Laboratories, UL–544, Standard for Medical and Dental Equipment, 1976, Reprinted 1985.

6. Illouz, Y. G., ''Illouz's Technique of Body Contouring by Lipolysis,'' *Clinics in Plastic Surgery*, 11:409–417, 1984.

7. Kesselring, U. K., ''Body Contouring with Suction Lipectomy,'' *Clinics in Plastic Surgery*, 11:393–498, 1984.

8. Dillerud, E., ''Suction Lipoplasty, A Report on Complications, Undesired Results, and Patient Satisfaction Based on 3,511 Procedures,'' *Plastic and Reconstructive Surgery*, 88:239–246, August 1991.

9. Dillerud, E., and L. L. Haheim, ''Long-term Results of Blunt Suction Lipectomy Assessed By Questionnaire Survey,'' *Plastic and Reconstructive Surgery*, 92:35–42, July 1993.

10. Dolsky, R. L., J. Newman, J. R. Fetzek, et al., ''Liposuction History, Techniques and Complications,'' *Dermatology Clinics of North America*, 5:313–333, 1987.

11. Teimourian, B. and W. B. Rogers, ''A National Survey of Complications Associated with Suction Lipectomy: A Comparative Study,'' *Plastic and Reconstructive Surgery*, 84:628–631, 1989.

12. Fredricks, S., ''Five-year Updated Evaluation of Suction-assisted Lipectomy,'' ASPRS Ad Hoc Committee on New Procedures, September 30, 1987.

13. Annual Book of American Society for Testing and Materials Standards, Medical Devices, vol. 13.01, 1088.

F 639–79 Standard Specification for Polyethylene Plastics for Medical Applications.

F 665–80 Standard Classification for Vinyl Chloride Plastics Used in Biomedical Application.

F 719–81 Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation.

F 720–81 Standard Practice for Testing Guinea Pig Maximization Test.

F 748–87 Standard Practice for Selecting Generic Biological Test Method for Materials and Devices.

F 749–87 Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit.

F 750–87 Standard Practice for Evaluating Material Extracts by Systemic Injection in the Mouse.

F 813–83 Standard Practice for Direct Cell Culture Evaluation of Materials for Medical Devices.

F 960–86 Standard Specification for Medical and Surgical Suction and Drainage Systems.

14. United States Pharmacopeia XXI, Biological Tests—Plastics.

15. ISO (International Organization for Standardization) 10079–1, Medical Suction Equipment, Part I, Electrically Powered Suction Equipment—Safety Requirements, 1993.

16. CSA (Canadian Standards Association), Standard Z168.11–94, Vacuum Devices Used for Suction and Drainage, 1994.

17. Grazer, F. M., ''Suction-Assisted Lipectomy: Its Indications, Contraindications, and Complications,'' *Year Book Medical Publishers*, 1984.

18. Ersek, R. A., J. Zambrona, G. S. Surak, et al., ''Suction-assisted Lipectomy for Correction of 202 Figure Faults in 101 Patients: Indications, Limitations, and Applications,'' *Plastic and Reconstructive Surgery*, 78:615–626, 1986.

19. Hetter, G. P., ''Optimum Vacuum Pressures for Lipolysis,'' *Aesthetic Plastic Surgery*, 8:23–26, 1984.

20. Christman, K. D., ''Death Following Lipectomy and Tissue,'' ''Neither Panacea of Humbug,'' *Postgraduate Medicine*, 75:124, 126, 128, 1984.

21. Courtiss, E. H., ''Suction Lipectomy: A Retrospective Analysis of 100 Patients,'' *Plastic and Reconstructive Surgery*, 73:780–796, 1984.

22. Badran, H. A., K. Z. Kodeara, and M. H. Mabrouk, ''Blood Conservation in Massive Suction Lipectomy,'' *Plastic and Reconstructive Surgery*, 92:1298–1304, 1993.

23. Hunter, G. R., R. O. Crapo, and T. R. Broadbent, ''Pulmonary Complications Following Abdominal Lipectomy,'' *Plastic and Reconstructive Surgery*, 71:809–817, 1983.

24. Backgrounder, ''Liposuction'' American Society of Plastic and Reconstructive Surgeons, July 1994.

25. Pitman, G. H., and B. Teimourian, ''Suction Lipectomy: Complications and Results by Survey,'' *Plastic and Reconstructive Surgery*, 76:65–72, 1985.

26. Tripartite Biocompatibility Guidance for Medical Devices, September 1986.

27. Clinical Practice Guidelines, Plastic and Maxillofacial Surgery, American Society of Plastic and Reconstructive Surgeons, Chapter L: Localized Adiposity, September 1993.

28. International Standard ISO–10993 Biological Evaluation of Medical Devices Part I Evaluation and Testing, 1995.

XIII. Request for Comments

Interested persons may, on or before February 11, 1997, submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 6, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–29066 Filed 11–12–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[Document Identifier: HCFA–1450]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Reinstatement, with change, of previously approved collection for which approval has expired; *Title of Information Collection:* Medicare Uniform Institutional Provider Bill Form HCFA–1450 (UB–92) and Instructions, and Supporting Regulations 42 CFR 424.5 (a) (5) (Claim for Payment), 42 CFR 424.32 (Basic Requirements for all Claims) and 42 CFR 412.60 (Diagnosis-Related Groups Classification and Weighting Factors); *Form No.:* HCFA–1450; *Use:* This form and instructions are standardized for use in the Medicare/Medicaid programs to apply for reimbursement for covered services. The HCFA–1450 is managed by the National Uniform Billing