FDC date	State	City	Airport	FDC No.	SIAP
10/09/98	ME	WATERVILLE	WATERVILLE ROBERT LEFLEUR	8/7138	VOR/DME OR GPS RWY 5 AMDT 7A...
10/09/98	NY	ANGOLA	ANGOLA	8/7144	GPS RWY 1 ORIG...
10/09/98	WI	APPLETON	OUTAGAMIE COUNTY REGIONAL	8/7127	ILS RWY 3, AMDT 16B...
10/09/98	WI	APPLETON	OUTAGAMIE COUNTY REGIONAL	8/7128	ILS RWY 29, AMDT 2...
10/09/98	WI	APPLETON	OUTAGAMIE COUNTY REGIONAL	8/7129	VOR/DME OR GPS RWY 21, ORIG...
10/09/98	WI	APPLETON	OUTAGAMIE COUNTY REGIONAL	8/7132	VOR/DME RWY 3, AMDT 8A...
10/09/98	WI	APPLETON	OUTAGAMIE COUNTY REGIONAL	8/7133	NDB OR GPW RWY 3, AMDT 14B...
10/09/98	WI	APPLETON	OUTAGAMIE COUNTY REGIONAL	8/7134	LOC BC RWY 11, AMDT 1...
10/09/98	WI	APPLETON	OUTAGAMIE COUNTY REGIONAL	8/7135	LOC BC RWY 21, ORIG...
10/09/98	WI	APPLETON	OUTAGAMIE COUNTY REGIONAL	8/7136	NDB RWY 29, AMDT 1...
10/09/98	WV	MOUNDSILLE	MARSHALL COUNTY	8/7145	VOR/DME OR GPS–A AMDT 1...
10/09/98	WV	PETERSBURG	GRANT COUNTY	8/7146	VOR/DME OR GPS–A AMDT 1...

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SOCIAL SECURITY ADMINISTRATION

20 CFR Part 422

RIN 0960–AE66

Listening-In to or Recording Telephone Conversations

AGENCY: Social Security Administration (SSA).

ACTION: Final rules.

SUMMARY: These final rules add regulations relating to the use of SSA's telephone lines. In the new regulations, we describe the limited circumstances under which SSA employees may listen-in to or record telephone conversations and the procedures we will follow in connection with this activity.

EFFECTIVE DATE: These final regulations are effective November 25, 1998.

FOR FURTHER INFORMATION CONTACT: Lois Berg, Legal Assistant, Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise Building, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–1713 or TTY (410) 966–5609. For information on eligibility, claiming benefits, or coverage of earnings, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778.

SUPPLEMENTARY INFORMATION:

Background

On August 8, 1996, the Federal Information Resources Management Regulation (FIRMR) was repealed. A provision of the FIRMR, section 201–21.603, related to listening-in to or recording telephone conversations. As a result of the repeal of the FIRMR, we are now promulgating our own regulations describing the limited circumstances under which SSA employees may listen-in to or record telephone conversations. These circumstances include law enforcement/national security, public safety, public service monitoring, and all-party consent situations. We also describe in these final regulations the procedures we will follow in determining the circumstances in which we will permit listening-in to or recording telephone conversations, who will listen-in to or record the conversations, and other policies and procedures which we will follow in connection with this activity.

SSA is committed to providing the public with the highest level of service by ensuring that information provided by SSA employees is delivered accurately and courteously. To ensure that commitment, we conduct monitoring of telephone calls over various designated SSA telecommunications lines as a training and mentoring tool.

We believe service observation is necessary to effectively perform SSA's mission. Therefore, we also conduct monitoring of telephone conversations to provide an objective assessment of SSA's telephone accuracy and courtesy. Data obtained through service observation are also used to comply with a congressional request that SSA provide Congress with information regarding teleservice center service levels on a continuing basis. This is done in the agency's Annual Financial Statement of Major Performance Measures. SSA's service observation activities are valuable to the public, not only because the data obtained are used to evaluate the accuracy of SSA's teleservice, but also because the service observation findings are used to make recommendations for improving teleservice procedures and processes. Data obtained through service observation are also used to respond to other oversight groups on how well SSA serves the public, for corrective action recommendation purposes, and for assisting in agency planning and decisionmaking.

Finally, SSA currently conducts recording of incoming calls on the emergency telephone lines assigned to SSA headquarters. We believe the recording of emergency calls is in the best interest of public safety and agency emergency service.

The main purpose of these final regulations is to inform the public and SSA employees of the circumstances under which SSA will listen-in to or record telephone conversations. The final regulations also contain language which differs from the repealed FIRMR which prohibited the annotating, e.g., writing down, of personal information such as a beneficiary's name, Social Security number, etc., when monitoring telephone calls. Because SSA has the responsibility to pay benefits correctly and to provide the public with accurate information, as well as to safeguard the trust funds, the final regulations will allow authorized employees to write down personal information obtained when listening-in to telephone calls. Annotated information obtained from public service monitoring will be used for programmatic or policy purposes; e.g., for recontacting individuals to correct or supplement information relating to benefits, for assessment of current/proposed policies and procedures, or to correct SSA records, etc.

Explanation of Final Regulations

We are adding a new subpart H to part 422 of our rules which will contain regulations relating to the use of SSA's telephone lines. This new subpart H contains three sections. In § 422.701, we

explain the scope and purpose of subpart H. In § 422.705, we explain when SSA employees may listen-in to or record telephone conversations. Finally, in § 422.710, we describe the procedures we will follow when we plan to listen-in to or record telephone calls, who will do it, and other policies and procedures which we will follow.

Comments on Notice of Proposed Rulemaking (NPRM)

On March 11, 1998, we published proposed rules in the **Federal Register** at 63 FR 11856 and provided a 60-day period for interested individuals and organizations to comment. We received two letters from organizations with comments. Following are summaries of the comments and our responses to them.

Comment: One commenter was of the opinion that the proposed regulations would have a chilling effect on the ability of SSA to effectively carry out its purpose of serving the public, especially in the matter of disability claims.

Response: SSA has conducted an ongoing evaluation of SSA's 800 number service since 1989. This evaluation involves the monitoring of 800 number telephone calls in order to ensure that the public is receiving accurate and courteous service. These data are reported to Congress each year in the Agency's Annual Financial Statement of Major Performance Measures and for training purposes.

Comment: One of the commenters indicated the use of a recording advising claimants that their conversations may be monitored could seriously undermine the confidence of the public in the entire system. However, the other commenter was pleased that the regulations contained language that the Agency will provide notice to the public about SSA telephone monitoring.

Response: To our knowledge, there has been no negative impact resulting from SSA's use of an upfront service observation message to let 800 number callers know that their calls may be monitored for quality assurance purposes.

Comment: One commenter indicated the regulations presume consent when there is none and provide absolutely no protection for employees.

Response: All callers whose telephone calls have the possibility of being monitored for quality assurance purposes receive a message before speaking with an SSA representative. If a caller does not wish to consent to monitoring, the caller can choose to terminate the call or request that the call not be monitored.

SSA and the American Federation of Government Employees have bargained and reached agreement on telephone monitoring practices which take place in the Agency. Affected employees are also aware of SSA telephone monitoring practices.

Comment: One commenter questioned the need for regulations that permit virtual total discretion in monitoring SSA telephone calls, which includes the use of unannounced service observation.

Response: The anonymity and lack of notice to employees when unannounced monitoring is employed provides SSA with an unbiased measurement of telephone service. Unannounced monitoring currently allows the Agency to provide an objective assessment of SSA's 800 number accuracy and courtesy which is submitted to Congress in the Agency's Annual Financial Statement of Major Performance Measures. These data are also used to respond to other oversight groups on how well SSA serves the public, for corrective action recommendations purposes and to assist in Agency planning and decisionmaking.

Comment: One commenter indicated the regulations should limit the number of people who can monitor telephone calls.

Response: The number of people assigned to monitor SSA telephone calls is a management decision based upon SSA's needs at any given time.

Comment: One commenter was of the opinion that unannounced listening to speaker phone conversations is not acceptable.

Response: SSA agrees that failing to identify all persons listening to a speaker phone conversation is discourteous, but courtesy issues are not an appropriate subject for these regulations. Moreover, there are times when discretion would be used, e.g., on whether to disrupt a speaker simply to notify all parties to the conversation that an individual who could overhear the conversation entered the area.

Comment: One commenter indicated SSA should use annotated information obtained from service observation only for programmatic and policy purposes.

Response: The regulation language on the use of annotated information is appropriate as most annotated information obtained from service observation will be used for programmatic or policy purposes.

Comment: One commenter indicated SSA should commit to taking corrective action and eliminate the phrase ''when possible''.

Response: It is not possible for SSA to commit to taking corrective action every time an incorrect action is taken or incorrect information is provided which could affect the payment of or eligibility to SSA benefits. This is because monitored calls do not always contain sufficient identifying information, such as a caller's name, address, telephone number and/or Social Security number, to allow corrective action to be taken.

For the reasons given in our responses to the comments on the proposed rules, we have not changed the text of the proposed rules. Therefore, we are publishing the proposed regulations unchanged as final regulations.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these final rules do not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, they were not subject to OMB review.

Regulatory Flexibility Act

We certify that these final regulations will not have a significant economic impact on a substantial number of small entities because they affect only individuals. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These final regulations impose no additional reporting or recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program Nos. 93.773 Medicare-Hospital Insurance; 93.774 Medicare-Supplementary Medical Insurance; 96.001 Social Security-Disability Insurance; 96.002 Social Security-Retirement Insurance; 96.003 Special Benefits for Persons Aged 72 and Over; 96.004 Social Security-Survivors Insurance; 96.005 Special Benefits for Disabled Coal Miners; and 96.006 Supplemental Security Income)

List of Subjects in 20 CFR Part 422

Administrative practice and procedure, Freedom of information, Organization and functions (Government agencies), Reporting and recordkeeping requirements, Social security.

Approved: October 13, 1998.

Kenneth S. Apfel,

Commissioner of Social Security.

For the reasons set out in the preamble, we are amending part 422 of chapter III of title 20 of the Code of Federal Regulations as follows:

PART 422—ORGANIZATION AND PROCEDURES

1. Subpart H is added to Part 422 to read as follows:

Subpart H—Use of SSA Telephone Lines

Subpart H—Use of SSA Telephone Lines

Authority: Secs. 205(a) and 702(a)(5) of the Social Security Act (42 U.S.C. 405 and 902(a)(5)).

§ 422.701 Scope and purpose.

The regulations in this subpart describe the limited circumstances under which SSA is authorized to listen-in to or record telephone conversations. The purpose of this subpart is to inform the public and SSA employees of those circumstances and the procedures that SSA will follow when conducting telephone service observation activities.

§ 422.705 When SSA employees may listen-in to or record telephone conversations.

SSA employees may listen-in to or record telephone conversations on SSA telephone lines under the following conditions:

(a) *Law enforcement/national security.* When performed for law enforcement, foreign intelligence, counterintelligence or communications security purposes when determined necessary by the Commissioner of Social Security or designee. Such determinations shall be in writing and shall be made in accordance with applicable laws, regulations and Executive Orders governing such activities. Communications security monitoring shall be conducted in accordance with procedures approved by the Attorney General. Line identification equipment may be installed on SSA telephone lines to assist Federal law enforcement officials in investigating threatening telephone calls, bomb threats and other criminal activities.

(b) *Public safety.* When performed by an SSA employee for public safety purposes and when documented by a written determination by the Commissioner of Social Security or designee citing the public safety needs. The determination shall identify the segment of the public needing protection and cite examples of the possible harm from which the public requires protection. Use of SSA telephone lines identified for reporting emergency and other public safety-related situations will be deemed as consent to public safety monitoring and recording. (See § 422.710(a)(1))

(c) *Public service monitoring.* When performed by an SSA employee after the Commissioner of Social Security or designee determines in writing that monitoring of such lines is necessary for the purposes of measuring or monitoring SSA's performance in the delivery of service to the public; or monitoring and improving the integrity, quality and utility of service provided to the public. Such monitoring will occur only on telephone lines used by employees to provide SSA-related information and services to the public. Use of such telephone lines will be deemed as consent to public service monitoring. (See § 422.710(a)(2) and (c)).

(d) *All-party consent.* When performed by an SSA employee with the prior consent of all parties for a specific instance. This includes telephone conferences, secretarial recordings and other administrative practices. The failure to identify all individuals listening to a conversation by speaker phone is not prohibited by this or any other section.

§ 422.710 Procedures SSA will follow.

SSA component(s) that plan to listen-in to or record telephone conversations under § 422.705(b) or (c) shall comply with the following procedures.

(a) Prepare a written certification of need to the Commissioner of Social Security or designee at least 30 days before the planned operational date. A certification as used in this section means a written justification signed by the Deputy Commissioner of the requesting SSA component or designee, that specifies general information on the following: the operational need for listening-in to or recording telephone conversations; the telephone lines and locations where monitoring is to be performed; the position titles (or a statement about the types) of SSA employees involved in the listening-in to or recording of telephone conversations; the general operating times and an expiration date for the monitoring. This certification of need must identify the telephone lines which will be subject to monitoring, e.g., SSA 800 number voice and text telephone lines, and include current copies of any documentation, analyses, determinations, policies and procedures supporting the application, and the name and telephone number of a contact person in the SSA component which is requesting authority to listen-in to or record telephone conversations.

(1) When the request involves listening-in to or recording telephone conversations for public safety purposes, the requesting component head or designee must identify the segment of the public needing protection and cite examples of the possible harm from which the public requires protection.

(2) When the request involves listening-in to or recording telephone conversations for public service monitoring purposes, the requesting component head or designee must provide a statement in writing why such monitoring is necessary for measuring or monitoring the performance in the delivery of SSA service to the public; or monitoring and improving the integrity, quality and utility of service provided to the public.

(b) At least every 5 years, SSA will review the need for each determination authorizing listening-in or recording activities in the agency. SSA components or authorized agents involved in conducting listening-in or recording activities must submit documentation as described in § 422.710(a) to the Commissioner of Social Security or a designee to continue or terminate telephone service observation activities.

(c) SSA will comply with the following controls, policies and procedures when listening-in or recording is associated with public service monitoring.

(1) SSA will provide a message on SSA telephone lines subject to public service monitoring that will inform callers that calls on those lines may be monitored for quality assurance purposes. SSA will also continue to include information about telephone monitoring activities in SSA brochures and/or pamphlets as notification that some incoming and outgoing SSA telephone calls are monitored to ensure SSA's clients are receiving accurate and courteous service.

(2) SSA employees authorized to listen-in to or record telephone calls are permitted to annotate personal identifying information about the calls, such as a person's name, Social Security number, address and/or telephone number. When this information is obtained from public service monitoring as defined in § 422.705(c), it will be used for programmatic or policy purposes; e.g., recontacting individuals to correct or supplement information relating to benefits, for assessment of current/proposed policies and procedures, or to correct SSA records. Privacy Act requirements must be

followed if data are retrievable by personal identifying information.

(3) SSA will take appropriate corrective action, when possible, if information obtained from monitoring indicates SSA may have taken an incorrect action which could affect the payment of or eligibility to SSA benefits.

(4) Telephone instruments subject to public service monitoring will be conspicuously labeled.

(5) Consent from both parties is needed to tape record SSA calls for public service monitoring purposes.

(d) The recordings and records pertaining to the listening-in to or recording of any conversations covered by this subpart shall be used, safeguarded and destroyed in accordance with SSA records management program.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 97N–0199]

General and Plastic Surgery Devices: Reclassification of the Tweezer-Type Epilator

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to reclassify the tweezer-type epilator from class III (premarket approval) to class I (general controls) when intended to remove hair. FDA is also exempting this device from the premarket notification (510(k)) requirements. This action is taken on the Secretary of Health and Human Services' own initiative based on new information. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This regulation is effective November 25, 1998.

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

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 1997 (62 FR 31771), FDA issued a proposed rule to reclassify the tweezer-type epilator from class III to class I based on new information respecting such device. FDA also proposed to exempt the device from premarket notification procedures.

Interested persons were given until September 9, 1997, to comment on the proposed rule. During the comment period, FDA received 10 comments.

One comment supported the proposed reclassification from class III to class I without providing any specific reason for endorsing the proposed reclassification. Nine comments were opposed to the proposed reclassification.

1. Two comments raised concerns about the device's safety. They stated that the device could cause burns and scars on the skin if it was improperly manufactured or used. One of these comments mistakenly believed that FDA was also proposing that the device be exempt from the current good manufacturing practices (CGMP's) regulation.

FDA agrees that improper manufacturing and use of the device could result in burns and scars on the skin. FDA also is clarifying for the record that the device was not proposed to be exempt from the CGMP's regulation (21 CFR part 820). FDA, however, believes that these risks can be controlled by general controls such as the CGMP requirements and labeling requirements.

2. Eight comments (from professional associations, a professional magazine, practitioners, a former patient, and a manufacturer) opposed reclassification because they believe the device is not effective in permanently removing unwanted hair. Four of these eight comments stated that there are no published scientific data demonstrating that the device permanently destroys hair. Three of these comments stated that hair is a dielectric material, i.e., a nonconductor of electricity so that it is impossible for electricity to descend through the hair to the dermal papilla and destroy it. Two of these three comments stated that there is no evidence that the device destroys the dermal papilla of hair. Another comment indicated that the effectiveness claims for the device are anecdotal and that there is much information that the device is ineffective.

FDA acknowledges that the published literature contains no evidence of statistically significant data showing that the device is effective in achieving permanent removal of hair. In the proposed rule, FDA described the one published study using the device (Ref. 1) that reported that the difference in the hair counts before and after treatment was not significant. Also in the proposed rule, the agency described the results of two unpublished studies (Refs. 2 and 3) and evaluated these results as being only suggestive of effectiveness in permanently removing hair. Thus, FDA agrees with the comments that there is no body of significant information establishing the effectiveness of the device to permanently remove hair. FDA, however, still believes that the device can be reclassified into class I, because claims for the device can be addressed by the misbranding provision of section 502 of the act (21 U.S.C. 352).

3. Three comments stated that the first sentence of the revised identification statement that ''the tweezer-type epilator is a device intended to remove hair by destroying the papilla of a hair'' is misleading because the phrase ''destroying the papilla of a hair'' is equivalent to stating the device permanently removes hair. They pointed out that this phrase is part of the identification statement of another device intended to remove hair, the needle epilator, 21 CFR 878.5350.

Although there is no universally accepted medical definition of what constitutes permanent removal of hair, FDA acknowledges that the phrase ''destroying the papilla of a hair'' is widely accepted by many to be equivalent to stating the device permanently removes hair. FDA now believes that the use of this phrase in the device identification statement was inaccurate, and in this final rule, is removing this phrase from the device identification.

4. Six comments related to the promotional material for the device. They stated that this material frequently contains false and misleading claims, specifically that the device is effective for permanent or long-term removal of hair. Five of these six comments also stressed that it is FDA's duty to protect the public from false and misleading claims regarding a product's effectiveness and that reclassification into class I could increase the number of such claims.

FDA takes seriously its responsibility to protect the public from false and misleading claims about a product's effectiveness; however, false and misleading claims may be controlled by