evaluation criteria in the program announcement and score the application prior to its submission, in order to gain a better sense of the application's quality and potential competitiveness in the ACYF review process.

For purposes of developing an application, applicants should plan for a project start date approximately 120 days after the closing date under which the application is submitted.

Two copies of the application plus the original are required. The Cover Page (included in the Application Kit) should be the first page of an application, followed by the one-page abstract.

Dated: July 9, 1997.

James A. Harrell,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 97-19009 Filed 7-17-97; 8:45 am] BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and **Families**

Agency Recordkeeping/Reporting Requirements Under Emergency **Review by the Office of Management** and Budget (OMB)

Title: National Directory of New Hires.

OMB No.: New.

Description: Public Law 104–193, the "Personal Responsibility and Work

Opportunity Reconciliation Act of 1996," requires the Office of Child Support Enforcement (OCSE) to develop a National Directory of New Hires (NDNH) to improve the ability of State Child support agencies to locate noncustodial parents and collect child support across State lines.

The NDNH will contain employment, wage and unemployment compensation data on all employees within the United States. Public Law 104–193 requires States and territories to periodically transmit new hire data received from employers to the NDNH, and to transit wage and unemployment compensation claims data to the NDNH on a quarterly basis.

Employers must report specified information (based on the IRS W-4 Form) on all new hires to State agencies for transmittal to the NDNH. States will transmit all data to the NDNH electronically. The purpose of the NDNH is to develop a repository of information on newly-hired employees, and on the earnings and unemployment compensation claims data on all employees, to provide the necessary information to locate child support obligors, and to establish and enforce child support orders.

As planned, the approximately 6.3 million United States' employers will submit approximately 60 million new hire records to the State Directory of New Hires (SDNH). If reports are submitted manually, employers must submit new hire reports not later than 20 days after the date the employer hires

the employee. If employers submit new hire reports electronically, reports must be submitted to the SDNH twice a month and not less than 12 days nor more than 16 days apart. The Štate shall have the option to set a civil money penalty for noncomplying employers.

The information will be entered into the data base maintained by the SDNH within five business days of receipt from an employer. Within three business days after the date information regarding a newly hired employee is entered into the SDNH, the information shall be furnished to the NDNH.

State agencies charged with the administration of the unemployment compensation program must submit to the NDNH approximately 140 million records quarterly. These State records contain the wages and unemployment compensation paid to individuals within the fifty States, Guam, Virgin Islands, Puerto Rico and the District of

Provided below are the proposed Record Layouts and Field Descriptions along with the Supplemental Specifications. The supplemental specifications contain additional explanation regarding format and content of items in the record specifications. The Record Layouts and Field Descriptions apply to the W-4, Quarterly Wage and Unemployment Compensation records respectively. Descriptions are also provided for header, data and trailer subrecords.

Respondents: States and Employers.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total bur- den hours
New Hire: Employers Not Currently Required to Report (manual reporting)*	*3,372,250	** 3,484	.0417 hours (2.5 min- utes).	489,930
New Hire: Employers Not Currently Required to Report (electronically) *	* 740,250	** 37,037	***.00028 hours (1 second).	7,677
New Hire: Multistate Employers' Registration Form	375,000	1	.050	18,750
New Hire: States Not Currently Requiring New Hire Reporting	29	**** 83,333	***** 266,668	644,445
New Hire: States Currently Requiring New Hire Reporting	25	**** 83.333	***** 70.741	147,376
Quarterly Wage & Unemployment Compensation	54	****** 4	.033	7.13

Estimated Total Annual Burden Hours: 1,308,185.

Footnotes:
The above burden estimates are based on the following assumptions and factors:
Twenty-five States already had a new hire reporting system in place before PRWORA was passed. Within those 25 States, on average, it is estimated that 75% of employers already report new hire data (based on the fact that some States require all employers to report, some require only targeted industries to report, and some are voluntary reporting programs). It is estimated that these

employers represent the same proportional number of new hire reports (75% of 25/54).

These estimates include the 25% remaining employers who do not report within those 25 States, in addition to all of the employers

within the remaining 29 States.

*Eighteen percent of all employers will report manually and 82% will report electronically (based on SSA's experience). The number of employers is based on the following calculation: the total number of employers (6,300,000) multiplied by 29/54 (the proportion of States that do not have new hire programs) plus the total number of employers multiplied by the number of employers not already reporting in the States that do have new hire programs (25% of 25/54). The result (4,122,500) is then broken down into two categories: those who report manually and those who report electronically.

**For the "Employers" tiers, "response" is defined as the number of new hire reports. Thirty percent of all new hire reports

will be reported manually and 70% will be reported electronically (based on SSA's experience).

*** Based on the assumption that employers reporting new hires electronically will most likely transmit their reports in a batch

file, thus significantly reducing the per-response burden.

****For the "States" tiers, "response" is defined as the number of transmissions to the NDNH. All States are required by law to transmit new hire data to the NDNH electronically, within three business days after entering the data into the SDNH. There are 250 business days per year. States will send a transmission once every three business days, which is equal to 83.333 transmissions

per year.

***** Based on the average number of reports per transmission and the average burden per new hire report. The average number of reports per transmission is calculated by dividing 32,222,220 (total number of new hire reports in those 29 States) by 29 (number of States). The result (1,111,111) is then divided by 83.333 (estimated number of transmissions per State, see above explanation). Based on this calculation, the average number of reports per transmission is 13,333.39 reports. The average burden per new hire report is estimated to be .02 hours (1.2 minutes), which is based on a range of two seconds to four minutes. The burden is estimated to be two seconds per report for the 70% of new hire reports submitted to the State electronically. This two second burden estimate is based on the same batch-file assumption as above, and includes data receipt and data transmission. If the State has to manually enter the new hire data before transmitting to the NDNH (which is the case for 30% of all new hire reports), the burden is estimated to be four minutes (based on the number of characters in a record). The average burden hours per report (.02) multiplied by the

average number of reports per transmission (13,333.39) is equal to the average burden hours per transmission (266.668).

****** Within the 25 States that already have a new hire reporting program in place, the burden is broken down into three categories. The total number of new hire reports for those 25 States is 27.8 million (46% of 60 million, or 25/54 times 60 million). Seventy-five percent of employers already submit to those States, so the incremental burden for that group is only the transmission to the NDNH (1 second per report). Twenty-five percent of employers do not already submit to those States, so the burden for that group is based on the same calculation as above: 30% of all new hire reports are reported manually (@ 4 minutes each) and

70% are reported electronically (@ 2 seconds each). The following table represents the exact formula for the calculation:

Types of reports	Number of new hire re- ports	Time per new hire report	Total time (hours)
Already Received From Employers (75%)	2,083,333	.000278 hours (1 second) .066667 hours (4 minutes) .000556 hours (2 seconds)	5787.0370 138888.8889 2700.6173

Total time for all three types of reports: 147,376.543 hours.

Total time per transmission (83.333) per State (25): 70.741 hours.

******** "Response" is defined here as the number of transmissions to the NDNH. States are required to transmit quarterly wage and unemployment compensation data four times a year.

Detailed Input Information

RECORD LAYOUTS AND FIELD DESCRIPTIONS FOR INPUT TO THE NATIONAL DIRECTORY OF NEW HIRE (NDNH)

Field name	Location position	Length	Alpha/ numeric	Description/remarks	Mandatory/optional	
	W4 Transmitter Record					
Record Identifier	1-2 3-4 5-13 14-15 16	2 2 9 2 1	A/N N A/N A/N A	'H4' State FIPS Code (for states only) Federal Agency Code (for federal agencies only) 'W4' for W4 data 'A' for active duty 'C' for civilian 'R' for reserves States may leave this field blank. Must be '01', controlled by OCSE	M. M for states. M for agencies. M. M for DOD.	
Data Stamp Batch Number	19–26 27–32	8	N N	Format=YYYYMMDD	M. M.	
Filler	33–801	769	A/N	unique. Spaces. To be used for future versions.	IVI.	
			W4 To	otal Record		
Record Identifier Data Record Count Filler	1–2 3–13 14–801	2 11 787	A/N N A/N	'T4' Total record count for transmission, including header and trailer records. Spaces. To be used for future versions	M. M.	
			W4 D	ata Record		
Record Identifier Employee SSN Employee Name:	1–2 3–11	2 9	A/N N	'W4' As reported by employee	M. M.	
First Name Middle Name	12–27 28–43	16 16	A	At least one character	M. O.	
Last Name	44–73	30	A	No Special characters	M.	

RECORD LAYOUTS AND FIELD DESCRIPTIONS FOR INPUT TO THE NATIONAL DIRECTORY OF NEW HIRE (NDNH)—Continued

1). Street Address (line 2). Street Address (line 2). Street Address (line 3). City	s less than 40 characters, do o one line. ers	M. O. O. M. M. M. M. O. M for foreign address. O. O. O. O. O. O. O. O.
Street Address (line 2). Street Address (line 154–193 40 A/N 3).	o one line. ors	O. M. M. M. O. M for foreign address. O. O. O. O. O. M.
Stréet Address (line 3). 194–218 25 A	ers s, except for hyphen y abbreviation umeric artment of Commerce FIPS tional Institute of Standards IPS PUB 10–4 (April 1995). to characters ormat—YYYYMMDD perritory abbreviation entification Number et, send the State EIN and 12 characters, left justify	M. M. M. O. M for foreign address. O. O. O. O. O. M.
City 194–218 25 A At least two character No special characters No special characters State 219–220 2 A Valid state or territory Zip Code (1) 221–225 5 N Must be numeric Zip Code (2) 226–229 4 A/N If present, must be numeric Employee Foreign Address Foreign Country 230–231 2 A/N Refer to U.S. Depactode manual, Name. Foreign Zip Code 257–271 15 A/N If present, at least two haracters Employee Date of Birth 272–279 8 A/N If present, numeric informations Employee State of Hire 280–287 8 A/N If present, numeric informations Employee State of Hire 288–289 2 A Alphabetic state or terminations Federal EIN 299–310 12 A/N If no FEIN is available if present and less themations Employer Name 311–355 45 A/N At least two characte FEIN address from W Employer Address: Street Address (line 1) 396–435 40 A/N A/N At least two characte FEIN address line into concentrate	s, except for hyphen	M. M. O. M for foreign address. O. O. O. O. O. M.
State	y abbreviation	M. O. M for foreign address. O. O. O. O. O. M.
Zip Code (1) 221–225 5 N Must be numeric Must be numeric<	umeric artment of Commerce FIPS tional Institute of Standards IPS PUB 10–4 (April 1995). o characters ormat—YYYYMMDD peritory abbreviation entification Number e, send the State EIN an 12 characters, left justify	M. O. M for foreign address. O. O. O. O. O. M.
Zip Code (2)	umeric	O. M for foreign address. O. O. O. O. O. M.
Employee Foreign Address Foreign Country Code. 230–231 2 A/N Refer to U.S. Depactode manual, Na and Technology, Foreign Country Shame. 232–256 25 A/N If present, at least two and Technology, Foreign Zip Code	artment of Commerce FIPS tional Institute of Standards IPS PUB 10–4 (April 1995). To characters	M for foreign address. O. O. O. O. O. M.
dress Foreign Country Code. Foreign Country Name. Foreign Zip Code	tional Institute of Standards IPS PUB 10–4 (April 1995). To characters	dress. O. O. O. O. O. M.
Foreign Country Name. 232–256 25 A/N	ormat—YYYYMMDD	O. O. O. M.
Employee Date of Birth Employee Date of Hire 272–279	ormat—YYYYMMDD	O. O. M.
Employee Date of Birth 272–279 8 A/N If present, numeric Femployee Date of Hire 280–287 8 A/N If present, numeric Femployee State of Hire 288–289 2 A Alphabetic state or temployer Idea State EIN	ormat—YYYYMMDD	O. O. M.
Employee Date of Hire 280–287 8 A/N If present, numeric Format—YYYYMMDI Employee State of Hire 288–289 2 A Alphabetic state or te Federal EIN	D	O. O. M.
Employee State of Hire 288–289 2 A Alphabetic state or te Federal EIN Federal EIN 290–298 9 N Federal Employer Ide State EIN 299–310 12 A/N If no FEIN is available If present and less the At least two characte FEIN address from W Employer Address: 311–355 45 A/N At least two characte FEIN address from W Employer Address: 356–395 40 A/N At least two characte FEIN address from W Street Address (line 396–435 40 A/N If your address line is not concentrate into conce	erritory abbreviationentification Numbere, send the State EINen 12 characters, left justify	M.
Federal EIN 290–298 9 N Federal Employer Ide State EIN 299–310 12 A/N If no FEIN is available if present and less the At least two characte FEIN address from W Employer Address: 311–355 45 A/N At least two characte FEIN address from W Employer Address: 356–395 40 A/N At least two characte work occurs from W 1). 396–435 40 A/N If your address line in not concentrate into concentrat	entification Numbere, send the State EINan 12 characters, left justify	M.
State EIN	e, send the State EIN ean 12 characters, left justify ers	
Employer Name 311–355 45 A/N At least two characte FEIN address from W Employer Address: Street Address (line 1). 356–395 40 A/N At least two characte FEIN address from W 1). Street Address (line 2). 396–435 40 A/N If your address line is not concentrate into concentrate into a not concentrate into concentrate into a not concentrat	rs	
Employer Address: Street Address (line 1). 356–395 40 A/N At least two characte 1). Street Address (line 2). 396–435 40 A/N If your address line is not concentrate into	v	
Street Address (line 1). 356–395 40 A/N At least two characte 1). 396–435 40 A/N If your address line is not concentrate into concentr		
Street Address (line 2). 396–435 40 A/N If your address line is not concentrate into	rs	M.
Street Address (line 3). 436–475 40 A/N . 3). 476–500 25 A At least two characte Valid state or territory Valid state or territory Must be numeric Zip Code (1) 503–507 5 N Must be numeric Zip Code (2) 508–511 4 A/N If present, must be numeric state or territory Must be numeric Employer Foreign Address: Foreign Country Code. 512–513 2 A/N Refer to U.S. Depart Code manual, Nariand Technology, F	s less than 40 characters, do o one line.	O.
City 476–500 25 A At least two characte Valid state or territory State 501–502 2 A Valid state or territory Zip Code (1) 503–507 5 N Must be numeric Zip Code (2) 508–511 4 A/N If present, must be numeric Employer Foreign Address: Foreign Country 512–513 2 A/N Refer to U.S. Depart code manual, Name and Technology, F		
State	ers	М.
Zip Code (1)	/ abbreviation	M.
Zip Code (2)		M.
Foreign Country Code. 512–513 2 A/N Refer to U.S. Departure of the code manual, National Technology, F	umeric	Ö.
	artment of Commerce FIPS tional Institute of Standards	M for foreign address.
Name.	o characters	О.
		О.
Employer Optional	e blank if only collecting one is a second address, it should where child support orders	O.
	s less than 40 characters, do	О.
1). Street Address (line	o one line.	O.
		O.
	o characters	Ο.
	or territory abbreviation	Ö.
	umeric	O.
	umeric	Ö.
Foreign Country 710–711 2 A/N Refer to U.S. Department of the Code.	artment of Commerce FIPS tional Institute of Standards	O.
	PS PUB 10–4 (April 1995). o characters	
		О.
Filler		

RECORD LAYOUTS AND FIELD DESCRIPTIONS FOR INPUT TO THE NATIONAL DIRECTORY OF NEW HIRE (NDNH)— Continued

Field name	Location	Length	Alpha/ numeric	Description/remarks	Mandatory/optiona
	<u>'</u>		Quarterly Wage	e Transmitter Record	
Record Identifier	1–2	2	Α	'HQ'	M.
Transmitter State Code	3–4	2	N	State FIPS Code (for states only)	M for states.
Transmitter Agency Code	5–13	9	A/N	Federal Agency Code (for federal agencies only)	M for agencies.
Fransmission Type	14–15	2	A/N	'QW' for quarterly wage data	M.
Department of Defense	16	1	A	'A' for active duty	M for DOD.
Code	-	· ·	^	'C' for civilian	IN IOI DOD.
Joue					
				'R' for reserves	
/anaisa Oantaal Nissakaa	47.40		A /A I	States may leave this field blank.	
/ersion Control Number	17–18	2	A/N	Must be '01', controlled by OCSE	
Date Stamp	19–26	8	N	Format=YYYYMMDD	M.
5	07.00			Must be current system date of file generation	
Batch Number	27–32	6	N	Sequential number to identify a submission as	M.
Filler	33–601	569	A/N	unique Spaces. To be used for future versions	
illei	33-001	309			
			Quarterly W	/age Total Record	
Record Identifier	1–2	2	Α	'TQ'	M.
Data Record Count	3–13	11	N	Total record count for transmission, including	M.
				header and trailer record.	
Filler	14–601	588	A/N	Spaces. To be used for future versions	
			Quarterly W	/age Data Record	
Record Identifier	1–2	2	Α	'QW'	M.
Employer SSN	3–11	9	Ñ	As reported by employee	M.
Employee Name:	_	_	1	As reported by employee	IVI.
First Name	12–27	16	Α		M.
riist ivaille	12-21	10	^	At least one character	IVI.
Middle Neme	20 42	16	_	No special characters	
Middle Name	28–43	16	A	If non-blank, must be at least one character No special characters	О.
Last Name	44–73	30	Α	At least one character	M.
Last Name	44 70	00	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	No special characters, except for hyphen	141.
Employee Wage Amount	74–84	11	N	Last two positions are decimal places	М.
imployee wage Amount	74 04	''	13	No negative values, zeroes are allowed	IVI.
				Gross amount paid with the quarter	
Reporting Period	85–89	5	N	Format—QYYYY for Calendar year	М.
reporting renor	05 05	3	13	Q=1 for Jan–Mar	IVI.
				Q=2 for Apr–Jun	
				Q=3 for Jul–Sep	
				Q=4 for Oct–Dec	
ederal EIN	90–98	9	N	Federal Employer Identification Number	M.
State EIN	99–110	12	A/N	If present and less than 12 characters, left justify	O.
Employer Name	111–155	45		At least two characters FEIN address	M.
		43	A/N		IVI.
Employer Address: Street Address (line	156–195	40	A/N	At least two characters	М.
1).	100-190	40	77/19	רו וטמטו נאיט טוומומטופוט	141.
Street Address (line	196–235	40	A/N	If your address line is less than 40 characters, do	О.
2).	190-233	40		not concentrate into one line.	J.
Street Address (line	236–275	40	A/N	not concentrate into one line.	О.
3).	200 213	40	, , , ,		J.
City	276-300	25	Α	At least two characters	М.
State	301–302	2	Ä	Valid state or territory abbreviation	M.
Zip Code (1)	303–307	5	Ñ	valid state of territory abbreviation	M.
Zip Code (1)	308–311	4	A/N	If present, must be numeric	O.
Employer Foreign Ad-	550 511	•			<u> </u>
dress:					
Foreign Country	312–313	2	A/N	Refer to US Department of Commerce FIPS code	M for foreign ad-
Code.				manual, National Institute of Standards and	dress.
				Technology, FIPS PUB 10-4 (April 1995).	
Foreign Country	314-338	25	A/N	If present, at least two characters	0
Name.					
Foreign Zip Code	339-353	15	A/N		0
Employer Optional Ad-				This address will be blank if only collecting one	
dress.				address. If there is a second address, it should	
				be the address where child support orders	
				po the address whole child capper cracic	

Record Layouts and Field Descriptions for Input to the National Directory of New Hire (NDNH)— Continued

Field name	Location position	Length	Alpha/ numeric	Description/remarks	Mandatory/optional
Street Address (line 1).	354–393	40	A/N	At least two characters if your address is less than 40 characters, do not concentrate into one line.	0
Street Address (line 2).	394–433	40	A/N		0
Street Address (line 3).	434–473	40	A/N		0
City	474–498	25	Α	If present, at least two characters	0
State	499–500	2	A	If present, valid state or territory abbreviation	ō
Zip Code (1)	501–505	5	A/N	If present, must be numeric	Ō
Zip Code (2)	506–509	4	A/N	If present, must be numeric	Ō
Employer Optional For- eign Address:					
Foreign Country Code.	510–511	2	A/N	Refer to U.S. Department of Commerce FIPS code manual, National Institute of Standards and Technology, FIPS PUB 10–4 (April 1995).	0
Foreign Country Name.	512–536	25	A/N	If present, at least two characters	0
Foreign Zip code	537–551	15	A/N		0
Filler	552–601	50	A/N	Spaces. To be used for future versions	
			UI Trans	smitter Record	
Record Identifier	1–2	2	Α	'HU'	М
Transmitter State Code	3–4	2	N	State FIPS (for states only)	M for states.
Transmitter Agency Code.	5–13	9	A/N	Federal Agency Code (for federal agencies only)	M for agencies.
Transmission Type	14–15	2	A/N	'UI' for unemployment insurance data	M
Filler	16	1	A/N		M for DOD.
Version Control Number.	17–18	2	A/N	Must be '01', controlled by OCSE	M
Date Stamp	19–26	8	N	Format=YYYYMMDD Must be current system date of file generation.	
Batch Number	27–32	6	N A/N	Sequential number to identify a submission as unique.	M
Filler	32–295	263	A/N	Spaces. To be used for future versions.	
D 111 00					
Record Identifier Data Record Count	1–2 3–13	2 11	A N	'TU' Total record count for transmission, including header and trailer record.	M M
Filler	14–295	282	A/N	Spaces. To be used for future versions.	
UI Data	Record				
Record Identifier	1–2	2	Α	'Ul'	М.
Claimant SSN	3–11	9	N	As reported by claimant	M.
First Name	12–27	16	A	At least one character	M.
Middle Name	28–43	16	A	If non-blank, must be at least one character No special characters	0.
Last Name	44–73	30	A	At least one character	M.
Claimant Address: Street Address (line 1).	74–113	40	A/N	Non-blank	M.
Street Address (line 2).	114–153	40	A/N	If your address line is less than 40 characters, do not concentrate into one line.	O.
Street Address (line 3)	154–193	40	A/N		О.
City	194–218	25	A	At least two characters	M.
State	219–220	2	Α	Valid state or territory abbreviation	M.
Zip Code (1)	221–225	5	N	Must be numeric	M.
Zip Code (2)	226–229	4	A/N	If present, must be numeric	Ο.

RECORD LAYOUTS AND FIELD DESCRIPTIONS FOR INPUT TO THE NATIONAL DIRECTORY OF NEW HIRE (NDNH)— Continued

Field name	Location position	Length	Alpha/ numeric	Description/remarks	Mandatory/optional
Benefit Amount	230–240	11	N	Last two positions are decimal places	M
Reporting Period	241–245	5	N	Q=1 for Jan—Mar Q=2 for Apr—Jun Q=3 for Jul—Sep Q=4 for Oct—Dec	М.
Filler	246–295	50	A/N	Spaces. To be used for future versions	

Supplement to New Hire Record Specifications

At the suggestion of the workgroup that assisted in developing the record specifications for the National Directory of New Hires (NDNH), this is an accompanying document that contains some additional clarification or explanation of items in the record specifications.

Mandatory Fields: The legislation mandates the collection of only the following six data elements from the W–4 form:

Employee SSN Employee Name Employee Address Employer Name Employer Address Employer ID number

On the W–4 record specifications these fields are marked with (M) to designate mandatory. There are three additional optional fields that are highly desirable for the New Hire data base. These are:

Employee Date of Birth Employee Date of Hire Employee State of Hire

While the legislation precludes the federal government from mandating the collection and retention of additional data elements, the states are not bound by those rules. The New Hire record specifications were developed in collaboration with State child support enforcement staff, State Employment Security Agency (SESA) staff, and federal and Department of Defense staff. Consequently, the specifications include additional data elements that will be

collected by the states and passed to the NDNH. There data elements will be used by the states and other authorized users of NDNH data.

Following are some clarifying statements that apply to all of the NDNH data elements and record formats.

- 1. All data is to be in EBCDIC format.
- 2. All alphanumeric data are to be in upper case.
- 3. All alphanumeric data are to be left justified.
- 4. All numeric data are to be right justified and zero filled.
- 5. All dates are to be in the Year 2000-compliant format of YYYYMMDD.
- 6. Name and city data are to be stripped of special characters except for the hyphen.
- 7. State and territory abbreviations in addresses should be the US Postal Service abbreviations
- 8. Name fields should not include suffixes such as "Jr.", "Sr.", and "III".
- 9. The NDNH will contain two addresses for the employer. The first address is that noted on the W-4 form. The second address is where child support orders should be sent. If only one address is available or known, use the first set of address data elements and leave the second set of data elements blank.
- 10. National standard codes are to be used for foreign country code abbreviations as assigned by the Department of Commerce FIPS codes (FIPS PUB 10–4).
- 11. For Quarterly Wage data, the employee wage amount is to be the gross amount paid during the quarter,

regardless of when the amount was earned.

- 12. For Unemployment Insurance data, the benefit amount is to be the gross amount paid within the quarter before any deductions or offsets are applied, regardless of when the benefit was earned or accrued.
- 13. WHEN IN DOUBT, SEND THE DATA. While the NDNH wants to receive clean, edited data, we want to receive all data in a timely manner. Consequently, if some data is missing or incomplete at the time of transmission, include the record(s) in the transmission. Hopefully, this will also make processing easier at the State level.
- 14. Output records returned from the NDNH will contain all of the input data sent to the NDNH and indications of errors or changes that took place at the federal level.
- 15. States have the option of receiving error records. The NDNH will maintain a matrix of which states want to be notified of errors and which do not

Input Records

When sending data to the federal level, there will be three record types in each transmission of data. These will include a header record, a series of data records, and concluded by a trailer record.

Header Record

The header record will be the first record in the data set and will contain the following fields.

Field name	Comments
Record Identifier	Enter 'H4' for W4 data. Enter 'HQ' for Quarterly Wage data.
Transmitter State Code	Enter 'HU' for Unemployment Insurance data. Refer to US Department of Commerce FIPS code manual, National Institute of Standards and Technology, FIPS PUB 10–4 (April 1995).

Field name	Comments
Transmitter Agency Code	Some federal agencies act as service bureaus for other federal agencies. Enter the Federal Employer Identification Number (FEIN) of the agency transmitting the data to the National Directory of New Hires.
Transmission Type	Identifies the type of data in this data set. Enter 'W4' for W4 data. Enter 'QW' for Quarterly Wage data.
Department of Defense Code	Enter 'UI' for Unemployment Insurance data. This field is mandatory only for DOD data transmissions. All others can ignore this field. DOD data is separated into several categories. This field indicates which category of data is being transmitted.
Version Control Number	Enter 'A' for active duty personnel. Enter 'C' for civilian personnel. Enter 'R' for reservist personnel. It is assumed that the system will be modified over time to accommodate future requirements. The version Control Number indicates which version of the system is in operation and will provide a means of communicating with data suppliers about record formats. Enter '01' until notified by OCSE to change this value.
Date Stamp	Enter the system generated date on the date the data set is transmitted to the federal level. Enter the date in the format YYYYMMDD.
Batch Number	A sequential number generated by the transmitting agency. This field is to uniquely identify a transmission. Do not repeat batch numbers.
Filler	Each record contains filler to be used for future versions of the record formats.

Total Record

Each data set is to be terminated with a Total Record which will contain the count of the total number of records transmitted in this data set.

Field name	Comments
Record Identifier	Enter 'T4' for W4 data. Enter 'TQ' for Quarterly Wage data. Enter 'TU' for Unemployment Insurance data.
Data Record Count	Enter the total number of records transmitted in this data set, including the header and trailer records. This will be used to verify that all records are received and processed.
Filler	Spaces. To be used for future versions of the system.

Data Record

Each of the data records for W4, Quarterly Wage, and UI is different in several ways. Following is further explanation of some of the data elements in those record layouts. See the Record Layout specifications for detailed information on all data elements.

Field name	Comments
Record Identifier	Enter 'W4' for W4 record.
	Enter 'QW' for Quarterly Wage record. Enter 'UI' for Unemployment Insurance record.
Foreign Address Data Elements	If an address supplied for the employee or employer is outside the United States, include the
Torogn Address Data Elements	Foreign County Code for the address, the Foreign Country Name, and the Foreign Zip Code.
Employee Wage Amount (QW)	For Quarterly Wage data, provide the gross amount paid to the employee during the quarter,
= mp.o/co mago / m.oum (Qm/) m.m.m.m.m.m.	regardless of when the amount was earned.
Reporting Period	Use the quarters that correspond to the calendar year rather than quarters that correspond to fiscal accounting periods. Use the format QYYYY where
	Q=1 for January–March
	Q=2 for April–June
	Q=3 for July–September
	Q=4 for October–December
Benefit Amount (UI)	The UI Benefit Amount is the gross amount paid within the reporting quarter before any with-
	holding offsets are applied. This amount should be the sum of benefits received from all
	programs tracked electronically by the State. However, only include those benefits that are
	housed in the same hardware environment. Do not include benefits from sources that must
	be translated or imported to the mainframe environment.

Output Records

FPLS will return records to the data transmitters when errors were detected. The states can elect to have these records returned for error resolution or not as they choose. Federal agencies, however, will receive all error records from each transmittal.

The record formats for the error records are identical to the input record provided by the submitter except that

error codes will be appended that explain the nature of the error. Errors can occur at the transmission level and at the individual record level.

Transmission Control Records

This is the output equivalent of the input TRANSMITTER RECORD and includes counts of records received, records rejected, error records returned, records posted to the National Directory of New Hires, records posted to the Suspense File and up to five Error Codes pertaining to the transmission level error conditions encountered.

Data Records

Each output version of the input DATA RECORD had appended to it up to five record level error codes that indicate the nature of the error encountered during editing. It also contains a Social Security Number Verification Indicator that indicates whether multiple valid SSNs were encountered during the SSN verification process. In addition, a corrected SSN is returned if during the SSN verification process the supplied SSN was determined to be incorrect and the verification procedure was able to provide the correct SSN.

Total Records

No transmission total records will be returned to the submitting State or federal agency

Additional Information

ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by August 15, 1997. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Driscoll at (202) 410–9313 or (202) 401–6465. Internet address: rdriscoll@acf.dhhs.gov

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street N.W., Washington, D.C. 20503, (202) 395–7316.

Dated: July 10, 1997.

Robert Driscoll,

Reports Clearance Officer.
[FR Doc. 97–18675 Filed 7–17–97; 8:45 am]
BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration [Docket No. 97E-0077]

Determination of Regulatory Review Period for Purposes of Patent Extension; GLYSETTM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for GLYSETTM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product. ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane. Rockville, MD 20857, 301-443-1382. SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and

Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product GLYSETTM (miglitol). GLYSETTM is indicated as an adjunct to diet to improve glycemic control in patients with non-insulindependent diabetes mellitus whose hyperglycemia cannot be managed with diet alone. GLYSETTM may also be used in combination with a sulfonylurea when diet plus either GLYSETTM or a sulfonylurea alone do not result in adequate glycemic control. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GLYSETTM (U.S. Patent No. 4,639,436) from Bayer Aktiengesellschaft, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 21, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of GLYSETTM represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for GLYSET™ is 4,900 days. Of this time, 4,544 days occurred during the testing phase of the regulatory review period, while 356 days occurred during the approval phase. These periods of time were derived from the following dates:

- 1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective: July 22, 1983. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on July 22, 1983.
- 2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: December 29, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for GLYSETTM (NDA 20–682) was initially submitted on December 29, 1995.
- 3. The date the application was approved: December 18, 1996. FDA has verified the applicant's claim that NDA